

EXHIBIT 2

Christopher E. Ramsey, M.D.

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
3 CHARLESTON DIVISION

4 IN RE: ETHICON, INC.) Master File No.
5 PELVIC REPAIR SYSTEM) 2:12-MD-02327
6 PRODUCTS LIABILITY)
7 LITIGATION) MDL No. 2327

8 _____
9)
10 THIS DOCUMENT RELATES TO) JOSEPH R.
11 PLAINTIFFS:) GOODWIN
12) U.S. DISTRICT
13 Mary Hendrix) JUDGE

14 Case No. 2:12-cv-00595)
15 Danni Laffoon)
16 Case No. 2:12-cv-00485)
17 Alfreda Lee)
18 Case No. 2:12-cv-01013)
19 Mary Holzerland)
20 Case No. 2:12-cv-00875)
21 Heather Long)
22 Case No. 2:12-cv-01275)
23 Donna Shepherd)
24 Case No. 2:12-cv-00967)
 Cheryl Lankston)
 Case No. 2:12-cv-00755)

18 CONTINUED
19 DEPOSITION OF
20 CHRISTOPHER E. RAMSEY, M.D.
21 Taken on behalf of the Plaintiff
22 April 7, 2016
23
24

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Christopher E. Ramsey, M.D.

1 Continued Deposition of CHRISTOPHER E.
 2 RAMSEY, M.D., taken on behalf of the Plaintiff,
 3 on April 7, 2016, at 7:48 a.m., at the Hampton Inn
 4 Suites Downtown Knoxville, 618 West Main Street,
 5 Knoxville, Tennessee, for all purposes under the Federal
 6 Rules of Civil Procedure.

7 The formalities as to caption,
 8 certificate, et cetera, are waived. All
 9 objections, except as to the form of the questions,
 10 are reserved to the hearing.

11 It is agreed that Lise S. Matthews,
 12 being a Notary Public and Certified Court Reporter
 13 for the State of Tennessee, may swear the witness,
 14 and that the reading and signing of the completed
 15 deposition by the witness is waived.

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Christopher E. Ramsey, M.D.

1 CHRISTOPHER E. RAMSEY, M.D.

2 was called as a witness, and after having been
3 previously sworn, testified as follows:

4

5 EXAMINATION BY MR. JONES:

6 Q. Doctor, we're back on the record.

7 Do you understand that?

8 A. Yes.

9 Q. You're still under oath; do you
10 understand that?

11 A. Yes.

12 Q. And you understand we're continuing the
13 deposition of you in regards to your opinions on
14 the TVT, TVT-O, and TVT-Secur device, correct?

15 A. Yes.

16 Q. Okay. Now, you brought with you some
17 materials yesterday; is that correct?

18 A. The boxes I have over here.

19 Q. Okay. And there are three boxes of
20 materials; is that correct?

21 A. Yes.

22 Q. And did you prepare those materials or
23 did your attorney?

24 A. I prepared them with the help of my

1 attorney.

2 Q. Okay. And those are materials that
3 your attorney sent you, correct?

4 A. Correct.

5 Q. And then you printed them off and
6 brought them, correct?

7 A. Correct, yes.

8 Q. And we'll go ahead and mark those three
9 boxes as Exhibit 12 for the record.

10 (Whereupon Exhibit 12A, 12B and 12C
11 were marked as an exhibit.)

12 BY MR. JONES:

13 Q. Did you bring any other materials with
14 you?

15 A. No.

16 Q. Didn't bring any invoices with you?

17 A. No. Other than what we already had
18 yesterday.

19 MR. JONES: Let's mark those. Get them
20 out and we'll mark them.

21 MR. MORIARTY: These are the case-
22 specific invoices.

23 BY MR. JONES:

24 Q. Okay. So you brought --

1 MR. MORIARTY: Either I lost or he has
2 not invoiced us for the general report.

3 MR. JONES: Okay.

4 THE WITNESS: I haven't invoiced it
5 yet.

6 BY MR. JONES:

7 Q. You have not invoiced --

8 A. No.

9 Q. -- sent any invoices to Ethicon in
10 regards to the work you've done for your general
11 expert opinions?

12 A. Not yet.

13 Q. Do you intend on sending those
14 invoices?

15 A. Yes.

16 Q. And, when you do send those invoices,
17 those will be invoices you have no issues with
18 sharing with us, correct?

19 A. Not at all.

20 Q. Okay. And we'll mark -- you did not
21 bring any invoices as they relate to your time
22 spent forming your general expert opinions in this
23 litigation today, correct?

24 A. Correct.

1 Q. You did bring some invoices related to
2 you forming your opinions on specific cases in this
3 litigation, though, correct?

4 A. Correct.

5 MR. JONES: Okay. We'll mark that as
6 Exhibit 13.

7 (Whereupon Exhibit 13 was marked as an
8 exhibit.)

9 BY MR. JONES:

10 Q. Is it fair to say Exhibit 13 represents
11 invoices that you've billed thus far in your work
12 for Ethicon as a litigation expert witness?

13 A. Yes.

14 Q. Okay. Did you bring any other
15 materials with you besides those three boxes?

16 A. No.

17 Q. Is TVT-Secur within the standard of
18 care, Doctor?

19 A. Yes.

20 MR. MORIARTY: Objection. Form.

21 Go ahead.

22 BY MR. JONES:

23 Q. It's your position that currently the
24 TVT-Secur device is within the standard of care for

1 doctors, correct?

2 A. Yes.

3 Q. In the United States, doctors can use
4 the TVT-Secur device on patients, correct?

5 MR. MORIARTY: Objection. Form.

6 THE WITNESS: If it was available, it
7 would be standard of care. It's not available, so
8 it can't be used.

9 BY MR. JONES:

10 Q. So because the TVT-Secur is not
11 available for use by physicians, it is not within
12 the standard of care today, correct?

13 A. I don't think I would say it's not
14 within the standard of care. I think that if it
15 was available, it would be in the standard of care.

16 Q. It's not -- the TVT-Secur device is
17 currently not available for use by surgeons on
18 patients, correct?

19 A. Correct.

20 Q. Because surgeons are unable to use the
21 TVT-Secur device on patients, it's not within the
22 standard of care for surgeons to use the device,
23 correct?

24 MR. MORIARTY: Objection. Form.

1 Go ahead.

2 THE WITNESS: No, I think it's still
3 within the standard of care.

4 BY MR. JONES:

5 Q. It's your opinion that the TVT-Secur
6 device is within the standard of care for
7 physicians inside the United States today?

8 A. Yes.

9 Q. Okay. Even though they can't use it,
10 it's within the standard of care; that's your
11 opinion?

12 A. It's within the standard of care.

13 Q. Okay.

14 A. The device is.

15 Q. Okay. Is Prolift within the standard
16 of care for physicians to use today?

17 MR. MORIARTY: Objection.

18 THE WITNESS: I can't make an opinion
19 on that. I don't use it.

20 BY MR. JONES:

21 Q. Okay. You're not going to be -- you
22 don't have any expertise whatsoever in transvaginal
23 mesh for use in pelvic organ prolapse, correct?

24 A. Correct.

1 Q. You don't have any experience in use
2 with transvaginal mesh for use -- for treatment of
3 pelvic organ prolapse, correct?

4 MR. MORIARTY: Objection. Asked and
5 answered.

6 Go ahead.

7 THE WITNESS: Correct.

8 BY MR. JONES:

9 Q. No expertise whatsoever in that field,
10 correct?

11 A. No.

12 Q. Okay. Now, you testified yesterday you
13 spent a total of 95 to 100 hours thus far in this
14 litigation, correct?

15 A. Correct.

16 Q. And at what rate are you charging per
17 hour?

18 A. \$500 an hour for review.

19 Q. Okay. So that's \$500 times 100 hours,
20 and we'll get the total amount of money that you
21 will bill for this case, correct?

22 A. Correct.

23 Q. \$500 times 100 is \$500,000, correct?

24 A. Not at all.

1 Q. No? How much is it? 50-?

2 A. Yes.

3 Q. Okay. So you'll bill \$50,000 total in
4 this litigation, correct?

5 A. Up to this point.

6 Q. Up to this point.

7 And you'll continue to do further work,
8 correct?

9 A. Yes.

10 Q. Okay. How much are you charging for
11 your deposition time?

12 A. \$750 an hour.

13 Q. So that will be in -- in addition to
14 the time you bill to Ethicon for your review of the
15 materials, correct?

16 A. Correct.

17 Q. How much did you bill for your time on
18 the two previous cases that you worked on for
19 Ethicon?

20 A. I'm not certain what I billed. It was
21 the same rates. I don't remember what --

22 Q. Okay.

23 A. -- what I charged.

24 Q. On the two prior cases that you worked

1 for Ethicon on related to transvaginal mesh, you
2 charged \$500 an hour, correct?

3 A. Four- or \$500 an hour at that time.

4 Q. Okay. And as you sit here today,
5 you're unable to tell us the total amount you
6 charged in those -- in your two prior cases with
7 Ethicon, correct?

8 A. I don't recall. I think I have a 1099
9 that we had on one of those, but I'm not -- I'm
10 not --

11 Q. Did you bring that 1099?

12 A. I think I have a copy of that.

13 Q. Okay. So you did bring other
14 materials.

15 Any other materials, I want to know
16 about them right now.

17 A. Not that I know of.

18 MR. JONES: Okay. Mr. Moriarty, are
19 there any materials besides this 1099 that you
20 brought today that he's not representing?

21 MR. MORIARTY: He's not representing
22 or --

23 MR. JONES: Are there any other
24 materials you brought with you so we can get

1 through this quicker today?

2 MR. MORIARTY: No.

3 MR. JONES: No. Okay.

4 BY MR. JONES:

5 Q. Other than this 1099, is there any
6 other materials, Doctor, that you brought?

7 A. No.

8 Q. Okay. What is this 1099 that you
9 brought with you today?

10 A. It's from 2015, tax return, from
11 Johnson & Johnson for \$3,800.

12 Q. Okay. So the only 1099 you brought
13 with you was for 2015, correct?

14 A. Correct. So that must have been the
15 2014 -- I don't -- I honestly don't know what
16 that -- which one that is. 2015 is what the 1099
17 is.

18 Q. Okay. And this represents that you
19 were paid \$3,800 by Johnson & Johnson, correct?

20 A. Yes.

21 Q. What was that \$3,800 for?

22 A. I believe it was for case reviews.

23 Q. So is it fair to say, starting in the
24 year 2003, up until the year 2014, you had a

1 consistent relationship with Ethicon in your role
2 providing consultant physician services, correct?

3 MR. MORIARTY: Objection.

4 Go ahead.

5 THE WITNESS: I wouldn't say
6 "consistent." I think I did one case in that --
7 2014 and one case in 2015.

8 BY MR. JONES:

9 Q. How about this: You started -- you
10 start in 2003 acting as a consultant physician for
11 Ethicon, correct?

12 A. I think I said 2005.

13 Q. We established yesterday that you
14 worked on the hand-assist device, correct?

15 A. Correct.

16 Q. That started in 2003?

17 A. That's true.

18 Q. Okay. So let me say that over.

19 We established yesterday that you
20 started working for Ethicon as a consultant in
21 2003, correct?

22 A. Correct.

23 Q. And you worked for Ethicon in 2004 as a
24 consultant, correct?

1 A. I can't remember. I would assume
2 that's correct. But I don't -- I don't remember.

3 Q. 2004 -- 2005 you worked for Ethicon as
4 a consultant, correct?

5 A. Possibly.

6 Q. 2006, you worked for Ethicon as a
7 consultant, correct?

8 A. Yes.

9 Q. 2007, you worked for Ethicon, correct?

10 A. Yes.

11 Q. 2008, you worked for Ethicon, correct?

12 A. Yes.

13 Q. 2009, you worked for Ethicon, correct?

14 A. Yes.

15 Q. 2010, you worked for Ethicon, correct?

16 A. Correct.

17 Q. And according to this 1099, in 2014,
18 you performed work for Ethicon, correct?

19 A. That's 2015. But --

20 Q. Okay.

21 A. -- 2014 too --

22 Q. So 2015 --

23 A. -- yes.

24 Q. 2015, you performed work for Ethicon,

1 correct?

2 A. Yes.

3 Q. 2014, you performed work for Ethicon,

4 correct?

5 A. Yes.

6 Q. Same for 2013?

7 A. Probably not.

8 Q. Probably not. So we've got from 2003

9 to 2012 you were a consultant for Ethicon, correct?

10 A. Correct.

11 Q. A paid consultant for Ethicon from 2002

12 to -- from 2003 to 2012, correct? I'll restate

13 that.

14 From 2003 to 2012, you were a paid

15 consultant for Ethicon, correct?

16 A. Between those years, I was.

17 Q. Okay. And then, starting back up in

18 2013, you once again renewed your relationship with

19 Ethicon as a consultant physician, correct?

20 MR. MORIARTY: Objection. Asked and

21 answered.

22 THE WITNESS: 2014.

23 BY MR. JONES:

24 Q. 2014. So following becoming board

1 certified in urology in 2004, but for two years of
2 your clinical practice, you served as a paid
3 consultant for Ethicon, correct?

4 A. Intermittently. I don't know if every
5 year between 2003 and 2005 I actually did every
6 year something for them. That was --

7 Q. Following your board certification in
8 urology in 2004, but for two years of your clinical
9 practice, you signed a contract with Ethicon as a
10 paid consultant, correct?

11 A. I'm not certain if it was every year.

12 Q. Okay.

13 A. I don't -- I don't -- I honestly don't
14 know.

15 Q. Did you bring those contracts with you?

16 A. No, I did not.

17 Q. Okay. And we've asked for those
18 contracts. And Ethicon has not produced them.

19 Do you know any way for us to get those
20 contracts?

21 A. I don't have a -- recall --

22 Q. Do --

23 A. -- I don't have a way to get those to
24 you.

1 Q. Okay. Do you have anything to hide in
2 regards to your relationship with Ethicon?

3 A. Not at all.

4 Q. There's nothing you have anything to
5 hide with the amount of contracts you signed with
6 Ethicon --

7 A. No, not at all.

8 Q. -- correct?

9 A. If Ethicon has them, then that's the
10 best way to find them.

11 Q. Okay. Ask Ethicon for those contracts,
12 correct?

13 A. Yes.

14 (Whereupon Exhibit 14 was marked as an
15 exhibit.)

16 BY MR. JONES:

17 Q. We'll mark the one 1099 you did bring
18 as Exhibit 14.

19 Starting in 2012, you were a consultant
20 for AMS, which is a company that manufactures
21 transvaginal mesh, correct?

22 MR. MORIARTY: Objection. Asked and
23 answered.

24 Go ahead.

1 THE WITNESS: I'm trying -- I don't --
2 I don't think that I did it in 2012, because I just
3 had started doing it toward the end of 2012, the
4 MiniArc-Precise. So it was probably 2013 that I
5 signed a contract with them.

6 BY MR. JONES:

7 Q. And but for Astora or AMS ceasing sale
8 of the A- -- or the AMS MiniArc device, March 31st,
9 2016, you were a consultant for AMS, correct?

10 A. I signed a contract with them. I never
11 did anything for them, though.

12 Q. Okay. But you signed a contract with a
13 mesh company besides Ethicon to act as a paid
14 consultant for them, correct?

15 A. Correct.

16 Q. At the time Ethicon contacted you --
17 first -- at the time Ethicon first contacted you to
18 act as a litigation expert witness, were you under
19 contract with AMS?

20 A. Yes.

21 Q. Is it true you've placed over 1,000
22 Ethicon mesh products in women?

23 A. That's the approximate number.

24 Q. You don't have an exact number?

1 A. I don't have an exact number.

2 Q. You've never gone back to your records
3 and tried to get an exact number?

4 A. No.

5 Q. That's not something Ethicon's asked
6 you to do?

7 A. No.

8 Q. Could it be more than 1,500?

9 A. I don't think so.

10 Q. More than 1,200?

11 A. I don't think so. I think a thousand
12 is right about -- is correct. Is approximately --
13 you know, plus or minus 50.

14 Q. Got it. Do you know, out of that 1,000
15 Ethicon mesh products you placed, which ones are
16 laser-cut mesh versus mechanical-cut mesh?

17 A. From my understanding, all these
18 TVT-Securs were laser cut, and some of the TVT
19 Obturators were laser cut, but I'm not sure which
20 ones or when that changed in the TVT Obturator.

21 Q. Is it fair to say you don't know, out
22 of the 1,000 slings you've placed, which ones are
23 laser-cut mesh and which ones are mechanical-cut
24 mesh?

1 MR. MORIARTY: Objection to form --

2 THE WITNESS: I would --

3 MR. MORIARTY: -- and asked and

4 answered.

5 THE WITNESS: I would say that I know

6 to a certain degree. I don't know exactly because

7 I don't know exactly how many I've done. But to a

8 certain degree, I know how many were done laser cut

9 and how many were not.

10 BY MR. JONES:

11 Q. When did Ethicon first start selling

12 laser-cut mesh?

13 A. I am not exactly certain.

14 Q. Okay. That would help you determine

15 which slings you put in that were laser-cut mesh

16 versus mechanical cut?

17 A. Which of the TVT Obturators.

18 Q. But you don't know when Ethicon first

19 started selling laser-cut mesh?

20 A. I can't recall. I've read it but I

21 don't remember.

22 Q. Do you have any idea?

23 A. I think around 2006, but I'm not sure.

24 Q. And what products did they start using

1 laser-cut mesh in?

2 A. I know the TVT-O; that's the one that I
3 used. And then the TVT-Secur when it came out.
4 I'm not sure if they changed the TVT Retropubic or
5 not.

6 Q. When you were using Ethicon mesh
7 products between the years of 2005 and 2012, were
8 you aware when you implanted an Ethicon mesh
9 product whether it was laser-cut mesh or
10 mechanical-cut mesh during that time period?

11 A. Yes.

12 Q. How did you know?

13 A. Because I had been informed that they
14 had changed the way that it had -- that they had
15 made their laser cut -- the way that they had
16 produced their mesh.

17 Q. Okay. What did they tell you?

18 A. That they stopped using manual cutting
19 and used laser cutting to --

20 Q. So at some point during your practice,
21 Ethicon came and told you, "We're not using
22 mechanical-cut mesh anymore in TVT-O," correct?

23 A. Correct.

24 Q. Did they tell you why they were not

1 using mechanical-cut mesh in TVT-O anymore?

2 A. No.

3 Q. They just told you they weren't using
4 it anymore, correct?

5 A. They told me they were doing it a
6 different way.

7 Q. "A different way" meaning what?

8 A. Cutting the mesh with a laser as
9 opposed to cutting it manually.

10 Q. So they come and say, "Dr. Ramsey,
11 we're going to start cutting the mesh in a
12 different way for the TVT-O product," correct?
13 That's what they --

14 A. Correct.

15 Q. And they say -- and they don't tell you
16 why they're going to do that, correct?

17 A. I don't remember them telling me why.

18 Q. Did you ask them why?

19 A. I don't think it really mattered to me.

20 Q. Didn't matter to you at all?

21 A. No.

22 Q. Okay. Is the mesh used in TVT-Secur
23 stiffer than the mesh you've used in TVT-O?

24 A. No.

1 Q. Not at all?

2 A. No.

3 Q. You don't recognize any difference in
4 the stiffness between the mesh used in TVT-Secur
5 and the mesh you used in TVT-O?

6 A. No.

7 Q. So when you pick them up and you pull
8 on them, there's no difference?

9 A. No.

10 Q. Okay. So do you have any experience
11 using mechanical-cut mesh with TVT-O?

12 A. Yes.

13 Q. Okay. Any difference between the
14 mechanical-cut mesh in the TVT-O versus the
15 laser-cut mesh in the TVT-O?

16 A. Not that I could tell, no.

17 Q. No difference whatsoever when you
18 picked them up and felt them?

19 A. No.

20 Q. No difference whatsoever between the
21 mechanical-cut mesh used in TVT-O and the laser-cut
22 mesh used in TVT-O when you simply touched the
23 mesh?

24 A. Correct.

1 Q. When you stretched the mesh, no
2 difference, correct?

3 A. No difference.

4 Q. Okay. Same stiffness, correct?

5 A. Correct.

6 Q. Did you notice any loss of particles
7 from the mesh when you used TVT products?

8 A. No.

9 Q. Did you notice any fraying of the mesh
10 when you used TVT products?

11 A. No.

12 Q. And have other surgeons ever
13 communicated to you concerns about the mesh used in
14 the TVT products fraying?

15 A. No.

16 Q. Losing particles?

17 A. No.

18 Q. Curling?

19 A. No.

20 Q. Roping?

21 A. No.

22 Q. Are you familiar with any of those
23 terms?

24 A. I'm familiar with the terms.

1 Q. And when did you first become familiar
2 with those terms?

3 A. When I started reading about the
4 litigation.

5 Q. And when would that have been? What
6 year?

7 A. Probably 2014.

8 Q. Prior to 2014, you weren't familiar
9 with the terms "curling," "roping," "fraying," or
10 "particle loss" of TVT mesh, correct?

11 A. Correct.

12 Q. What's the pore size of the mesh used
13 in TVT-Secur?

14 A. It's about 1,300 microns, 1,376 maybe.

15 Q. What are -- what are you basing that
16 on? Who told you that?

17 A. The measurements.

18 Q. Who told you that?

19 A. There's an article in Moalli that
20 showed the different sizes of the particles -- or
21 sizes of the pores.

22 Q. Where did Dr. Moalli get that
23 information from?

24 A. I'm assuming that it's published in --

1 with the -- with the -- Ethicon has measured it.
2 The other companies have measured it. Or he
3 measured it. I don't know.

4 Q. That's an assumption that you're
5 making, correct?

6 A. I read the article, and there was a
7 graph in the article. I can see it pretty clearly
8 in my brain right now.

9 Q. Okay. And so in that article it says
10 Ethicon provided this measurement, correct?

11 A. I don't remember what --
12 (Reporter interruption for
13 clarification.)

14 BY MR. JONES:

15 Q. Ethicon provided -- in the article that
16 you remember so clearly, it says Ethicon provided
17 the pore size measurements, correct?

18 A. In the article --

19 MR. MORIARTY: Objection to form.

20 THE WITNESS: In the article I remember
21 so clearly, I don't remember where they got the
22 information.

23 BY MR. JONES:

24 Q. Okay. Okay.

1 So you would be making an assumption
2 where they got that information from, correct?

3 A. I'm -- reading the article and the
4 information was presented there. Now, I'm taking
5 it at their face value, that what they put in there
6 is accurate information.

7 Q. Okay.

8 A. That's how you get information.

9 Q. And you're familiar with this article
10 by Dr. Moalli, correct?

11 A. Yes.

12 Q. And you know that Dr. -- you've -- you
13 referred to Dr. Moalli today and yesterday as a
14 male, but you know that Dr. Moalli is a female,
15 correct?

16 A. I honestly don't know. I know
17 Dr. Moalli.

18 Q. Okay. You know Dr. Moalli?

19 A. I know Dr. Moalli's name.

20 Q. Okay.

21 A. And I don't know her first name --

22 Q. Okay.

23 A. -- but I know that.

24 Q. Between 2006 and 2011, you were a

1 high-use users of Ethicon mesh products, correct?

2 A. Correct.

3 Q. Would you consider yourself a high-use
4 user of the AMS MiniArc-Precise device?

5 A. I believe I am.

6 Q. Do you agree with the FDA's position on
7 mini-slings?

8 MR. MORIARTY: Objection.

9 Go ahead.

10 THE WITNESS: I guess it depends on
11 what position you're talking about. I don't -- I
12 don't know if -- that's not -- that's pretty
13 general.

14 BY MR. JONES:

15 Q. How about this: You know that the
16 FDA's position is that the safety and efficacy of
17 the TVT-Secur device has not been demonstrated,
18 correct?

19 A. They -- they represent articles that
20 have shown that it doesn't have as good efficacy in
21 some articles.

22 Q. Yes or no? You know that the FDA's
23 position on TVT-Secur is that the safety and
24 efficacy of TVT-Secur has not been demonstrated?

1 MR. MORIARTY: Objection. Form.

2 THE WITNESS: I don't think that they
3 bring into question the safety. They bring into
4 question the efficacy.

5 BY MR. JONES:

6 Q. You know that the FDA's position on
7 TVT-Secur is that the efficacy of TVT-Secur has not
8 been adequately demonstrated, correct?

9 A. I don't think that they're saying that
10 it has not been adequately demonstrated. I think
11 they're saying that they would like to see more
12 information to show that it has efficacy.

13 Q. Do you agree or disagree that the FDA's
14 current position is that the safety of the
15 TVT-Secur device has not been adequately
16 demonstrated?

17 MR. MORIARTY: Objection.

18 THE WITNESS: I don't think that's
19 their position.

20 BY MR. JONES:

21 Q. Do you agree or disagree that the FDA's
22 position is that the efficacy of the TVT-Secur
23 device has not been adequately demonstrated?

24 A. Again, I think that they have concerns

1 that the efficacy needs to be further studied to
2 show that it is efficacious.

3 Q. And you know that surgeons in the field
4 of urology hold the position that the safety of the
5 TVT-Secur device has not been adequately
6 demonstrated, correct?

7 MR. MORIARTY: Objection. Form.

8 THE WITNESS: I don't -- I don't agree
9 with that. I think they think it's safe.

10 BY MR. JONES:

11 Q. My question is, you know that some
12 surgeons hold that position, though, correct?

13 A. I don't know that.

14 Q. You've never talked to any surgeons
15 whatsoever that hold the position that the safety
16 of the TVT-Secur device has not been adequately
17 demonstrated?

18 A. I don't think the safety has been
19 brought into question at all.

20 Q. You've never talked to one surgeon
21 that's questioned the safety of the TVT-Secur
22 device?

23 A. No.

24 Q. Have you talked to a single surgeon

1 that's questioned the efficacy of the TVT-Secur
2 device?

3 A. Yes.

4 Q. And I assume you've talked to surgeons
5 that are concerned that the efficacy of the
6 TVT-Secur has not been adequately demonstrated,
7 correct?

8 A. Again, I think that surgeons think that
9 it needs to be -- there needs to be further studies
10 showing the efficacy of it.

11 Q. Surgeons believe there need to be
12 further studies to show the efficacy of the
13 TVT-Secur device, correct?

14 A. Yes.

15 Q. Do you know what a 522 order is?

16 A. I'm aware of it.

17 Q. You're aware of what it is?

18 A. Yes, sir.

19 Q. What is it?

20 A. It's an order by the FDA to conduct
21 further testing to show efficacy in a product.

22 Q. That's your understanding of what a 522
23 order is?

24 A. Yes.

1 Q. How many 522 orders have been issued to
2 Ethicon in regards to transvaginal mesh?

3 MR. MORIARTY: Objection. Form.

4 Go ahead.

5 THE WITNESS: I don't --

6 MR. MORIARTY: Are you talking about
7 slings or --

8 THE WITNESS: In general --

9 MR. JONES: No. I'm talking about
10 transvaginal mesh.

11 THE WITNESS: In general? I'm not
12 certain.

13 BY MR. JONES:

14 Q. Okay. How about slings?

15 A. The only one I know of is with
16 TVT-Secur.

17 Q. You know that the TVT-Secur device was
18 subject to a 522 order, correct?

19 A. Yes.

20 Q. What did the 522 order for the
21 TVT-Secur device say?

22 A. The FDA wanted Ethicon to conduct
23 studies on the TVT-Secur to show further efficacy,
24 because they were concerned about the efficacy of

1 the TVT-Secur.

2 Q. What year is this?

3 A. That was 2011 or '12.

4 Q. In 2012, Ethicon was asked to perform
5 additional safety studies on the TVT-Secur device,
6 correct?

7 A. No.

8 Q. In 2012, Ethicon was asked to perform
9 additional studies on the TVT-Secur device,
10 correct?

11 A. Correct.

12 Q. Ethicon made a decision to not conduct
13 any additional studies on the TVT-Secur device in
14 2012, correct?

15 A. Correct.

16 Q. Ethicon made a decision, instead of
17 running additional studies on the TVT-Secur device
18 like requested, they would stop selling the device,
19 correct?

20 A. Correct.

21 Q. The reason Ethicon stopped selling the
22 TVT-Secur device in 2012 was because they decided
23 not to run additional testing on the TVT-Secur
24 device, correct?

1 MR. MORIARTY: Objection --

2 THE WITNESS: Correct.

3 MR. MORIARTY: -- form.

4 Go ahead.

5 THE WITNESS: Correct.

6 BY MR. JONES:

7 Q. The decision -- the decision by Ethicon
8 to stop selling the TVT-Secur device in 2012 was a
9 business decision, correct?

10 A. I believe it was.

11 Q. We talked about 20 events that you
12 proctored as an Ethicon consultant yesterday; is
13 that correct?

14 A. Approximately.

15 Q. Okay. Of the 20 events that you
16 proctored for Ethicon, how many of those involved
17 TVT-Secur?

18 A. Probably two-thirds of them.

19 Q. Two-thirds of your proctoring events
20 for Ethicon involved the TVT-Secur device, correct?

21 A. Yes.

22 Q. Did you -- at those proctoring events,
23 did you instruct physicians on how to place the
24 TVT-Secur device?

1 A. Yes.

2 Q. When you instructed surgeons how to
3 place a TVT-Secur device at Ethicon events, did you
4 ever instruct physicians to place the TVT-Secur
5 device in a way that was inconsistent with the
6 instructions for use?

7 A. I didn't do any instructions at TVT --
8 at Ethicon events.

9 Q. At these proctor events where you
10 instructed surgeons on how to place the TVT-Secur
11 device, did you ever instruct the surgeons in a way
12 that was inconsistent with the instructions for use
13 for the TVT-Secur device?

14 A. No.

15 Q. Every time you instructed another
16 surgeon on how to place a TVT-Secur device, your
17 instructions were consistent with the instructions
18 for use for the TVT-Secur device, correct?

19 A. Correct.

20 Q. Never went off the grid on the
21 TVT-Secur IFU, correct?

22 MR. MORIARTY: Objection. Form.

23 Go ahead.

24

1 BY MR. JONES:

2 Q. Never went rogue?

3 A. Never went rogue?

4 Q. Correct.

5 A. No, never went rogue.

6 Q. And there weren't any instructions
7 that -- on how to place the TVT-Secur device that
8 you would use at these proctor events that weren't
9 in the instructions for use for TVT-Secur, correct?

10 MR. MORIARTY: Objection. Asked and
11 answered.

12 Go ahead.

13 THE WITNESS: Correct.

14 BY MR. JONES:

15 Q. You're familiar with the "TVT-Secur
16 Cookbook"? Are you familiar?

17 A. That sounds familiar.

18 Q. Are you familiar with the "TVT-Secur
19 Pearls"?

20 A. Yeah, sounds familiar.

21 Q. I take it you're familiar with the
22 FDA's public health notification on transvaginal
23 mesh?

24 A. Yes.

1 Q. Are you familiar with the FDA's 2011
2 panel on transvaginal mesh?

3 A. The FDA's panel? I'm not certain about
4 the panel.

5 Q. Are you aware that in 2011 the FDA
6 convened a panel of experts to weigh in on the
7 safety of transvaginal mesh?

8 MR. MORIARTY: Objection.

9 Go ahead.

10 THE WITNESS: I know they had a
11 notification. I'm not certain how that
12 notification was developed.

13 BY MR. JONES:

14 Q. And I take it that you're familiar with
15 the FDA's current position on midurethral slings,
16 correct?

17 A. Yes.

18 Q. And you understand that the FDA states
19 that the safety of midurethral slings has been
20 shown in clinical trials up to one year, correct?

21 A. I'm not certain "up to one year."

22 Q. You're familiar with the FDA's current
23 position on mini-slings, correct?

24 A. Yes.

1 Q. As you sit here today, do you -- does
2 anything stand out to you in regards to the FDA's
3 current position on mini-slings that you disagree
4 with?

5 A. No.

6 Q. Okay. Are you familiar with the
7 Cochrane analysis?

8 A. Yes.

9 Q. Are you familiar with the Cochrane
10 analysis on mini-slings?

11 A. Yes.

12 Q. Are you familiar with the Cochrane
13 analysis on TVT-Secur?

14 A. Yes.

15 Q. Do you agree or disagree with
16 Cochrane's conclusions on the safety and efficacy
17 of the TVT-Secur device?

18 A. I agree with the safety conclusions.
19 The -- and I would say I agree with what they're
20 saying about the efficacy.

21 Q. Okay. Does the AUGS position statement
22 apply to mini-slings?

23 A. I can't remember specifically if it
24 applies to mini-slings or not.

1 Q. Do you know who Dennis Miller is?

2 A. That's a comedian.

3 Q. Do you know who Dennis Miller is in
4 regards to the AUGS statement?

5 A. No.

6 Q. Do you know who Howard Goldman is?

7 A. No.

8 Q. Charlie Nager?

9 A. No.

10 Q. Paul Tulikangas?

11 A. No.

12 Q. Eric Robener?

13 A. No.

14 Q. Are you aware of the recent Lin
15 articles discussing cancer from a transvaginal
16 mesh?

17 MR. MORIARTY: Objection. Go ahead.

18 THE WITNESS: Not specifically a Lin
19 article.

20 BY MR. JONES:

21 Q. Have you seen any internal studies by
22 Ethicon where they have tested the mesh used in TVT
23 for degradation?

24 MR. MORIARTY: I'm sorry. Could you

1 read that back?

2 (Whereupon the previously mentioned
3 question was read back by the reporter.)

4 MR. MORIARTY: Okay, thanks.

5 THE WITNESS: I've seen so many studies
6 that -- the TVT mesh in general for degradation?

7 BY MR. JONES:

8 Q. Correct.

9 A. The information I've seen, it shows it
10 doesn't degrade.

11 Q. Okay. I don't want to know about any
12 studies other than the testing that Ethicon's done.
13 Let me limit my question to testing Ethicon has
14 done internally at Ethicon.

15 A. I can't specifically recall that at
16 this point.

17 Q. Okay. Are you familiar with the
18 seven-year dog study Ethicon conducted examining
19 whether Prolene degrades inside the human body or
20 not?

21 A. I don't know that study.

22 Q. Are you familiar with the Guidoin study
23 by Ethicon examining whether Prolene sutures
24 degrade inside the human body?

1 A. I can't recall that one.

2 Q. Are you familiar with an article by
3 Professor Clavé discussing whether mesh degrades
4 inside the human body?

5 A. I can't recall that one.

6 Q. Are you familiar with any of the
7 research out of the University of Missouri by
8 Drs. Costello or Ramshaw discussing degradation of
9 the mesh inside the human body?

10 A. No.

11 Q. Are you familiar with the ICS and IUGA
12 mesh complication classification system?

13 A. No.

14 Q. Have you reviewed the material safety
15 data sheet for the TVT mesh?

16 A. Yes.

17 Q. And when did you review that?

18 A. I actually reviewed a little bit of it
19 last night.

20 Q. Okay. Before last night, had you
21 reviewed it?

22 A. Yes.

23 Q. And since you reviewed it last night,
24 you know that it discusses the presence of sarcomas

1 in rats exposed to Prolene material, correct?

2 MR. MORIARTY: Objection.

3 Go ahead.

4 THE WITNESS: It discusses the
5 potential for sarcoma in rats using sheet Prolene.

6 BY MR. JONES:

7 Q. You know that oxidizing agents
8 naturally -- naturally occur inside a woman's
9 vagina, correct?

10 A. Yes.

11 Q. Do you know at what levels?

12 A. No.

13 Q. Do you know what oxidizing agents?

14 A. Peroxides. Other than that, not
15 specifically.

16 Q. You know that in a 2011 FDA public
17 health notification, the FDA stated that
18 complications from transvaginal mesh are not rare,
19 correct?

20 MR. MORIARTY: Objection. Form.

21 Go ahead.

22 THE WITNESS: That's what the statement
23 said.

24

1 BY MR. JONES:

2 Q. Do you agree or disagree that
3 complications from transvaginal mesh are not rare?

4 MR. MORIARTY: Objection. And this is
5 supposed to be about TVT.

6 BY MR. JONES:

7 Q. Go ahead and answer.

8 MR. MORIARTY: You're mixing.
9 Go ahead.

10 THE WITNESS: I was going to say, are
11 you talking about slings or are you talking about
12 POP mesh?

13 BY MR. JONES:

14 Q. That's okay. We'll move on.

15 Well, you know that erosions from the
16 mesh used in TVT are not rare, correct?

17 A. I would say erosions are very rare.

18 Q. Do you know who Axel Arnaud is?

19 A. No.

20 Q. Would you defer to the expertise of
21 medical directors at Ethicon as to the safety and
22 efficacy of the TVT products?

23 A. No.

24 Q. Would you defer to any of the medical

1 directors at Ethicon as to the adequacy of the
2 warnings in the TVT IFUs?

3 A. I think that the IFUs are adequate, and
4 so I -- I -- I think that anything that's been
5 discussed inside of Ethicon doesn't really pertain
6 to what would apply to me.

7 Q. The discussions Ethicon medical
8 directors had inside the company about the warnings
9 in the TVT IFUs are not relevant to you, correct?

10 A. I think they need to have these
11 discussions and be very candid within themselves
12 about what needs to be put in an IFU before they
13 put it in the IFU.

14 So once it is in the IFU -- and I've
15 looked at the IFU and I think the IFU is
16 adequate -- whatever went on within Ethicon doesn't
17 pertain to me. I mean, that's all internal
18 business decisions that don't apply to me
19 clinically.

20 Q. Do you think Ethicon makes business
21 decisions on what to include in its TVT IFUs?

22 A. I don't think they make business
23 decisions to include what goes in the IFU.

24 Q. How many times has Ethicon changed the

1 TVT-Secur IFU?

2 A. The TVT-Secur IFU?

3 Q. Yeah.

4 A. Honestly, I don't know how many times
5 they've changed the TVT-Secur IFU.

6 MR. JONES: I'll mark for the record
7 Exhibit 15.

8 (Whereupon Exhibit 15 was marked as an
9 exhibit.)

10 BY MR. JONES:

11 Q. Take a look at Exhibit 15, Doctor.

12 A. Okay.

13 Q. Turn -- what is Exhibit 5?

14 A. It says "Gynecare TVT" Tension-Free
15 Vaginal Tape, 2015.

16 Q. Okay. Do you recognize --

17 A. It's instructions for use.

18 Q. You recognize Exhibit 15 as the
19 Gynecare TVT instructions for use, correct?

20 A. For TVT.

21 Q. For TVT Retropubic, correct?

22 A. Does it say "retropubic"? It just says
23 "TVT vaginal tape."

24 Q. You recognize Exhibit 15 as the

1 Gynecare tension-free vaginal tape IFU, correct?

2 A. Yes.

3 Q. Turn to page 4.

4 A. Okay.

5 Q. At page 4, you see in the Gynecare TVT

6 IFU the heading "Warnings and Precautions,"

7 correct?

8 A. Yes.

9 Q. And on the next page, you see the

10 heading "Adverse Reactions," correct?

11 A. Correct.

12 Q. Under "Adverse Reactions" in the TVT

13 IFU, chronic pain is listed, correct?

14 A. Yes.

15 Q. Is chronic pain a risk associated with

16 the use of the TVT devices?

17 MR. MORIARTY: Objection.

18 THE WITNESS: It's associated with any

19 procedure for stress incontinence.

20 BY MR. JONES:

21 Q. Okay. I'm not asking about any other

22 procedures but TVT. So just answer the question.

23 Is chronic pain a risk associated with

24 the TVT devices?

1 MR. MORIARTY: Objection. Asked and
2 answered.

3 Go ahead.

4 THE WITNESS: It's a particular -- it's
5 a potential risk for any vaginal surgery.

6 BY MR. JONES:

7 Q. Okay. Yes or no or you can't answer
8 the question? Yes or no, is chronic pain a
9 potential risk associated with the TVT devices?

10 A. With other procedures and the TVT
11 device.

12 Q. I'm not asking about any other TVT --
13 or about any devices but the TVT. So just answer
14 the question as it relates to TVT, okay?

15 Yes or no? Is chronic pain a risk
16 associated with the use of the TVT devices?

17 MR. MORIARTY: Objection. Form.

18 Go ahead.

19 THE WITNESS: Again, you know, any
20 vaginal surgery has a potential for chronic pain.
21 So it's not just with a TVT device. It's -- it's
22 with any vaginal surgery for stress incontinence.
23 So not just with -- I mean, you're saying --
24

1 BY MR. JONES:

2 Q. Can you answer the question "yes" or
3 "no"? Yes or no, is chronic pain a risk associated
4 with the TVT devices?

5 MR. MORIARTY: Objection. Form.
6 Go ahead.

7 THE WITNESS: It is associated with the
8 placement of TVT and other devices.

9 BY MR. JONES:

10 Q. The question was can you answer that
11 question "yes" or "no"? It sounds like you can't,
12 correct?

13 A. I guess I can't answer your question
14 "yes" or "no."

15 Q. Okay. Thank you.

16 Can you answer "yes" or "no" whether
17 pain with intercourse in which some patients
18 never -- may not resolve is a risk associated with
19 the use of TVT devices?

20 MR. MORIARTY: Objection. Form.

21 THE WITNESS: With any --

22 MR. MORIARTY: Go ahead.

23 THE WITNESS: With any vaginal
24 procedure.

1 BY MR. JONES:

2 Q. Can you answer that question "yes" or
3 "no"?

4 A. The same as the previous questions.

5 Q. So you can't answer "yes" or "no"
6 whether pain with intercourse which may not resolve
7 is a risk associated with the use of the TVT
8 device?

9 A. Again, specifically, with the TVT
10 device, it's -- it is with any vaginal surgery.

11 Q. One or more revision surgeries may be
12 necessary to treat the adverse reactions from TVT
13 devices, correct?

14 A. And any vaginal surgery.

15 Q. Did I read that correctly?

16 A. Yes.

17 Q. One or more revision surgeries may be
18 necessary to treat these adverse reactions listed
19 in the TVT IFU, correct?

20 A. That's correct.

21 Q. "Prolene mesh is a permanent implant
22 that integrates into the tissue. In cases in which
23 the Prolene mesh needs to be removed in part or
24 whole, significant dissection may be required."

1 Did I read that correctly?

2 A. Yes.

3 Q. Is that listed under the "Adverse
4 Reaction" section in the TVT IFU?

5 A. Yes.

6 Q. And do you agree with that statement?

7 A. Yes.

8 Q. Explain what "significant dissection"
9 means.

10 A. In order to dissect out the entire
11 mesh, depending on which TVT was used -- in this
12 case -- I think we're talking about a retropubic
13 procedure -- it would require significant
14 dissection along the vaginal wall and then
15 posterior to the pubic bone and the suprapubic
16 tissues. So that would be a significant dissection
17 if it would need to be removed.

18 Q. "Neuromuscular problems, including
19 acute and/or chronic pain in the groin, thigh, leg,
20 pelvic, and/or abdominal area may occur."

21 Did I read that correctly?

22 A. Yes.

23 Q. Is that a risk associated with the use
24 of the TVT devices?

1 MR. MORIARTY: Objection. Form.

2 Go ahead.

3 THE WITNESS: Again, as I said before,
4 it's a risk with any vaginal surgery.

5 BY MR. JONES:

6 Q. Okay. And you know that neuromuscular
7 problems in the abdominal area may occur with every
8 single pelvic surgery? Do you know that as you sit
9 here today?

10 A. I would say neuromuscular problems can
11 happen with any surgery for stress incontinence
12 that requires the suspension, passing of
13 instruments from above to below or below to above.

14 Q. That's not the question I asked.

15 I asked about neuromuscular problems in
16 the abdominal area with any pelvic surgery.

17 A. Not with -- not with every pelvic
18 surgery.

19 Q. Okay. "Overcorrection, i.e. too much
20 tension applied to the tape, may cause temporary or
21 permanent lower urinary tract obstruction."

22 Did I read that correctly?

23 A. Yes.

24 Q. Is that a risk unique to the TVT

1 devices?

2 A. No.

3 Q. "Mesh extrusion, exposure, or erosion
4 into the vagina or other structures or organs is an
5 adverse reaction associated with the use of TVT
6 devices," correct?

7 A. Yes.

8 Q. Is that a risk unique to the TVT
9 devices?

10 MR. MORIARTY: Objection. Form.

11 THE WITNESS: I would say that there
12 can be -- that's -- I would say that there can be a
13 mesh -- mesh -- or graft exposure for other types.
14 But as far as mesh exposure, yes, it would be a
15 specific potential complication for the TVT.

16 BY MR. JONES:

17 Q. Okay. It can occur with other pelvic
18 mesh surgeries, correct?

19 A. Mesh. As we described, graft surgeries
20 too when using autologous graft or other -- other
21 grafts, including porcine and suspension with
22 sutures, permanent sutures that can be exposed or
23 extrude or erode into the vagina.

24 Q. Is a medical device company required to

1 list the frequency of the adverse reactions in the
2 IFU?

3 A. No.

4 Q. Should a medical device company list
5 the frequency of the adverse reactions in the IFU?

6 A. No.

7 Q. Should a medical company list the
8 severity of the adverse reactions in the IFU?

9 A. No.

10 Q. Should a medical company list the
11 duration of the adverse reactions listed in the TVT
12 IFU?

13 A. Not in the IFU, no.

14 Q. Should a medical device company make
15 any statements about the duration of adverse
16 reactions in the IFU?

17 A. No.

18 Q. Should Ethicon make any statements
19 about the specific design features unique to the
20 TVT mesh in the IFU?

21 MR. MORIARTY: Objection. Form.

22 Go ahead.

23 THE WITNESS: The specific design
24 features on how to use it, yes.

1 BY MR. JONES:

2 Q. What about specific design features
3 that may have an impact on patient safety?

4 A. Yes.

5 Q. Ethicon should list the design features
6 of the TVT mesh that may have an impact on patient
7 safety in the IFU, correct?

8 A. Yes.

9 Q. Have you learned of any risk associated
10 with the use of the TVT device through peer-
11 reviewed medical literature?

12 A. Yes.

13 Q. What risk?

14 A. That's pretty broad.

15 Q. Name one.

16 (Reporter interruption for
17 clarification.)

18 BY MR. JONES:

19 Q. Name one.

20 A. Repeat the question.

21 Q. Name one risk that you learned from
22 medical literature associated with the use of TVT
23 devices.

24 A. Exposure of the graft.

1 Q. All right. Name another.

2 A. Specific to the -- to the TVT or just
3 in general for stress urinary incontinence repair?

4 Q. TVT.

5 A. Specific to TVT?

6 Q. Yeah.

7 A. So exposure of the graft.

8 Q. Is that it?

9 A. Specific -- specific to the TVT.

10 Q. That's the only risk you've learned of
11 through the medical literature?

12 A. Yes.

13 Q. And you learned that -- exposure of the
14 mesh as a risk of the TVT device, you learned that
15 through the medical literature?

16 A. Medical literature, conferences,
17 experience, my clinical experience, discussion with
18 other physicians.

19 Q. Other than exposure of the mesh, have
20 you learned of any other risk associated with the
21 use of the TVT device?

22 A. Specific to the TVT device?

23 Q. Other than exposure of the mesh, have
24 you learned of any risk uniquely associated with

1 the use of TVT devices?

2 A. No other risk.

3 Q. Have -- at this point, have you been
4 asked by Ethicon to amend your report?

5 A. Which report?

6 Q. Your TVT general report.

7 A. No.

8 Q. Have you been asked to make changes to
9 any of your other reports?

10 A. No.

11 Q. Have you been asked to supplement any
12 reports?

13 A. No.

14 Q. Do you know why Ethicon makes their
15 mesh blue?

16 A. I don't know for sure why.

17 Q. Why do you think they make their mesh
18 blue?

19 A. So that if there is an exposure, it's
20 easier to identify and to remove.

21 Q. But that's not something you know to a
22 reasonable degree of medical certainty, correct?

23 A. I think that's the reason why.

24 Q. Hmm?

1 A. I think that's the reason why.

2 Q. Do you agree that the safety and
3 effectiveness of multi-incision slings is well
4 established in clinical trials that followed
5 patients for up to one year?

6 A. More than one year.

7 Q. So you disagree?

8 A. I agree with that and more.

9 Q. But as a standalone statement, you
10 think it's unfair to limit it to one year?

11 A. I think it's -- that statement is
12 correct.

13 Q. Do you think the safety and
14 effectiveness of single-incision slings is well
15 established in clinical trials?

16 A. There are clinical trials that show
17 good efficacy of these slings in experienced
18 surgeons.

19 Q. Okay. You know that there are clinical
20 trials that show low efficacy of mini-slings,
21 correct?

22 A. There are both.

23 Q. You know there are more clinical trials
24 that show inadequate efficacy of mini-slings?

1 A. I don't know that there are more
2 articles; I know there are articles.

3 Q. Fair mix of both, correct?

4 A. There's -- yes.

5 Q. There's a balance of both?

6 A. Yes.

7 Q. Some articles say good things about
8 mini-slings; some articles say bad things about
9 mini-slings, correct?

10 MR. MORIARTY: Objection. Form.

11 THE WITNESS: I don't know if they say
12 good or bad about them. I think they talk about
13 how effective they are. That's, you know, not a
14 qualification of good or bad.

15 BY MR. JONES:

16 Q. Okay.

17 A. Evil or saintly.

18 Q. Have you ever reported any Ethicon mesh
19 complications?

20 A. No.

21 Q. No. Not to Ethicon?

22 A. Not to Ethicon.

23 Q. Not to the FDA?

24 A. No.

1 Q. Do you have a patient registry that
2 tracks your TVT patients?

3 A. I do not.

4 MR. JONES: I'll mark for the record
5 Exhibit 16.

6 (Whereupon Exhibit 16 was marked as an
7 exhibit.)

8 BY MR. JONES:

9 Q. I'm not going to ask you too many
10 questions about this, but take a quick look at this
11 document.

12 And to speed us up, I'll direct you to
13 page -- starting at page 3, the email from Andrew
14 Meek, December 1st, 2006.

15 A. Okay.

16 MR. MORIARTY: I'm sorry --

17 THE WITNESS: It's 4, isn't it?

18 MR. MORIARTY: You said --

19 MR. JONES: It's on ETH.MESH.00136908.

20 THE WITNESS: Okay. Is the -- is the
21 bulk of the email the next page, or is it the one
22 above it?

23 BY MR. JONES:

24 Q. Yeah. Yeah.

1 MR. MORIARTY: I'm sorry. Which one?

2 Are you talking about this one, Nate, or a
3 different one?

4 Okay. The one at the bottom.

5 THE WITNESS: But that goes on to the
6 next page, right?

7 MR. JONES: Right. Right. The
8 doctor's following along.

9 BY MR. JONES:

10 Q. All right. Is this an email dated
11 December 2006, Dr. Ramsey?

12 A. Where is that? Which one is that?

13 Yeah.

14 Q. This email is dated December 2006,
15 right?

16 A. December 1, 2006.

17 Q. Thank you. And the email's sent from
18 Andrew Meek, correct?

19 A. Yes.

20 Q. And then on the "To" line, lists the
21 recipients of this December 2006 Ethicon email,
22 correct?

23 A. Yes.

24 Q. Okay. And ceramsey@charter.net is one

1 of the emails listed in the recipient lines,
2 correct?

3 A. Where is that?

4 Okay.

5 Q. And that's an email you currently use
6 or used to use, correct?

7 A. No. I use chartertn.net.

8 Q. Okay. And were you a TVT-Secur
9 preceptor?

10 A. Yes.

11 Q. Okay. And does this indicate by the
12 ceramsey@charter.net that you would have been an
13 intended recipient of this email?

14 A. Possibly, but that wasn't my email
15 address.

16 Q. Okay. We'll go through some more
17 emails later on in the day with that email address
18 and see if we can get to the bottom of that.

19 A. Okay.

20 Q. I'll represent to you that there's
21 emails that you've sent from that email address
22 that will show --

23 A. Oh, that I have?

24 Q. Yeah, if that helps you.

1 A. Without "tn"?

2 Q. Yeah. Okay?

3 A. Okay.

4 Q. So we've got this email dated 2006,
5 correct?

6 A. Yes.

7 Q. And the subject line is "TVT-Secur
8 Preceptor Conference Call."

9 A. Okay.

10 Q. Is that correct?

11 A. Yes.

12 Q. It says, "Dear Preceptors, Four months
13 after the launch of TVT-Secur experience has
14 accumulated among you that needs to be shared and
15 taught."

16 Did I read that correctly?

17 A. Yes.

18 Q. And then there's a conference call set
19 up for December 14th at 6:00 p.m., correct?

20 A. It looks like that's what they want to
21 do.

22 Q. Okay. Did you participate in that
23 conference call?

24 A. Not to my recollection.

1 Q. "All preceptors are highly encouraged
2 to attend the conference call."

3 Did I read that correctly?

4 A. Yes.

5 Q. You don't know whether you attended the
6 conference call or not?

7 A. I can't -- I can't remember. It's ten
8 years ago -- or almost ten.

9 Q. "The larger base of experience we have
10 to draw from and share the information with, the
11 more valuable this forum will be."

12 Did I read that correctly?

13 A. Yes.

14 Q. So the more preceptors that
15 participate, the more useful it will be, correct?

16 A. Correct.

17 Q. You don't know whether you participated
18 or not, though?

19 A. I really can't remember.

20 Q. Do you know who Andy Meek is?

21 A. I don't -- the name sounds familiar,
22 but I don't remember him.

23 Q. You don't remember the professional
24 education manager at Ethicon?

1 A. No.

2 Q. I asked you earlier if you were
3 familiar with the TVT-S Cookbook.

4 Do you recall that question?

5 A. Yes, it sounds familiar.

6 Q. Okay. Sounds familiar.

7 And I also asked you about the
8 TVT-Secur Pearls.

9 You said that sounded familiar as well,
10 too, correct?

11 A. Yes.

12 Q. And you see part of the agenda for the
13 conference call is "Copy reviewed Pearls\tips,"
14 correct?

15 A. Correct.

16 Q. Do you know who Dr. Lucente is?

17 A. I know the name.

18 Q. Do you know who Dr. Karram is?

19 A. I don't recognize that name.

20 Q. Do you know that Dr. Karram and
21 Dr. Lucente are consultants for Ethicon?

22 A. I know that Lucente is. I don't recall
23 Karram.

24 Q. How do you know Dr. Lucente is a

1 consultant for Ethicon?

2 A. I just remember his name involved with
3 the original rollout of the TVT-Secur, just -- it's
4 a distinctive name. I remember it.

5 Q. Yeah. Is he a well-known pelvic floor
6 surgeon?

7 A. I honestly don't know if he's well
8 known. I don't know exactly what he does. I don't
9 even know if he's a gynecologist or a urologist.

10 Q. Okay. Okay. Put that one away.

11 We talked yesterday about Ethicon's
12 sales rep Jason Martin, correct?

13 A. Yes.

14 Q. And you met Mr. Martin in 2011,
15 correct?

16 A. I might have met him beforehand, just
17 in social situations.

18 Q. Okay. What is Carleo's in Knoxville?

19 A. Carleo's?

20 Q. Carleo's?

21 A. Carleo's? Gosh. I don't remember. It
22 sounds like a restaurant, but I'm not sure.
23 Carleo's?

24 Q. Who is Dr. Newport?

1 A. John-Paul Newport. He's one of my
2 partners.

3 Q. Did Dr. Newport ever contact you or
4 discuss with you about getting trained on
5 TVT-Secur?

6 A. He may have.

7 Q. You don't have any memory of
8 Dr. Newport approaching you about using the
9 TVT-Secur device?

10 A. Not specifically him approaching me
11 about the TVT-Secur device.

12 Q. Okay. And what do you recall?

13 A. I don't recall. You know, we were --
14 we're partners, so we see each other frequently and
15 talk about cases frequently, talk about different
16 procedures frequently. So there's no way I can
17 pinpoint a specific conversation about one device.

18 Q. Are you currently partners?

19 A. Yes.

20 Q. Do you know what products Dr. Newport
21 currently uses?

22 A. I am actually not certain what he uses.

23 Q. Is Dr. Congleton a partner of yours?

24 A. Yes.

1 Q. You understand that Dr. Congleton is
2 also acting as a litigation expert witness for
3 Ethicon in this litigation?

4 A. Yes.

5 Q. You understand that Dr. Congleton is
6 also a consultant for Ethicon?

7 A. Yes.

8 Q. Are there any other partners that are
9 consultants for Ethicon besides yourself and
10 Dr. Congleton?

11 A. No, not that I'm aware of.

12 Q. How about other mesh companies?

13 A. No, not that I'm aware of.

14 Q. Any of your partners place more TVT
15 devices than you?

16 A. More TVTs in general? Any TVT device?

17 Q. Yes.

18 A. Dr. Congleton and Dr. Cameron and
19 Dr. Parker are probably all fairly close in my
20 practice. Dr. Nicely does as well. So, I mean,
21 we're all fairly close as to how many we -- we
22 place each year.

23 Q. If I limit it to TVT-Secur, none of
24 your partners have approached the numbers of

1 TVT-Securs that you've implanted, though, correct?

2 A. I don't know how many Dr. Parker did.

3 He did -- he would do TVT-Secur until it was

4 discontinued. So he was probably fairly similar.

5 He didn't start it as soon as I did. So overall,

6 probably not, but at the end, I would say yearly he

7 was close to what I was doing.

8 Q. Did you introduce Dr. Parker to the

9 TVT-Secur device?

10 A. I may have.

11 Q. Did you introduce Dr. Newport to the

12 TVT-Secur device?

13 A. Probably not. He might have been shown

14 that in residency. I'm not sure. I can't remember

15 when he came to our practice, honestly, but it was

16 after 2006. So he probably already knew about the

17 TVT-Secur.

18 (Whereupon Exhibit 17 was marked as an
19 exhibit.)

20 MR. JONES: I think we're on Exhibit

21 17. I think so.

22 MR. MORIARTY: Do you have an extra?

23 BY MR. JONES:

24 Q. All right. Doctor, Exhibit 17 is a

1 2011 email, correct?

2 A. Yes.

3 Q. Between Jason Martin and Scott Finley?

4 A. Okay.

5 Q. Correct?

6 A. Yes.

7 Q. Jason Martin at this point in time was

8 your Ethicon sales representative, correct?

9 A. Probably.

10 Q. And Scott Finley is -- was the -- Jason

11 Martin's manager, correct?

12 A. Yes.

13 Q. And you've known Scott Finley for a

14 long time, correct?

15 A. Yes.

16 Q. And does this indicate that you met

17 Jason Martin at Carleo's for the first time in

18 2011?

19 A. It looks like that's the -- that's what

20 he says.

21 Q. Okay. Do you have any reason to doubt

22 that?

23 A. No.

24 Q. Okay. Jason Martin writes, "Anyway, I

1 saw Dr." -- "Anyway, I saw Ramsey today in clinic.
2 I didn't bring this up or make any promises. He
3 told me to get with Dr. Newport because he wants to
4 get proctored on TVT-Secur. Newport is currently
5 doing the TVT-O that I know of, but wants to learn
6 TVT-Secur."

7 Did I read that correctly?

8 A. Yes.

9 Q. Does this indicate that you told Jason
10 Martin that Dr. Newport wanted to get proctored on
11 TVT-Secur?

12 A. It -- it says that I mentioned that to
13 him. It doesn't say that was the first time
14 that -- that Newport -- that he wanted to get with
15 Newport.

16 Q. You told Ethicon that Dr. Newport
17 wanted to get proctored on TVT-Secur, correct?

18 A. That's what this email says.

19 Q. And then, following this, eventually
20 you did proctor Dr. Newport on the TVT-Secur
21 device, correct?

22 A. I probably did.

23 Q. Now, the last paragraph Jason Martin,
24 your Ethicon sales rep, writes, "FYI, am sponsoring

1 their monthly meeting to present data on TVT

2 Abbrevio, but it's not until June."

3 A. Okay.

4 Q. Did I read that correctly?

5 A. Yes.

6 Q. What monthly meeting was Ethicon
7 sponsoring?

8 A. That's our monthly business meeting
9 that we have.

10 Q. And this is with your clinic?

11 A. This is with our -- my group.

12 Q. Your group?

13 A. My practice.

14 Q. Your practice group?

15 A. Yes.

16 Q. Tennessee Urology Associates?

17 A. TUA.

18 Q. TUA is your practice --

19 A. Tennessee Urology Associates, yes.

20 Q. TUA, your practice group, holds a
21 monthly business meeting, correct?

22 A. Our -- our group -- our pod does, yes.

23 Q. And at times Ethicon sponsored your
24 practice group's monthly business meeting, correct?

1 MR. MORIARTY: Objection. Form.

2 THE WITNESS: We have a dinner that --
3 that we have before or during the meeting, and
4 usually we will have a -- somebody -- you know,
5 some type of -- either a pharmaceutical
6 representative or a product representative bring us
7 the dinner, and then they'll give us a little
8 presentation, little ten-minute presentation before
9 our meeting.

10 BY MR. JONES:

11 Q. At your practice group's monthly
12 meetings, it's customary to have a sales
13 representative present information to you, correct?

14 A. Not over the last couple of years.

15 Q. Before the last couple of years, it was
16 customary for your practice group to have a monthly
17 business meeting where a sales representative would
18 attend and present information, correct?

19 A. Sometimes.

20 Q. Okay. And before the last couple of
21 years, it was customary for your practice group to
22 hold business meetings where at times Ethicon would
23 sponsor that meeting, correct?

24 A. At times -- I don't remember how many

1 times they did it, but it would -- it wouldn't be
2 unusual they would come in one -- once or twice.

3 Q. Wouldn't be unusual for Ethicon to come
4 in once or twice to your practice group's monthly
5 meetings, correct?

6 A. Correct.

7 Q. Wouldn't be unusual for Ethicon to
8 sponsor your practice group's monthly business
9 meeting, correct?

10 A. Correct.

11 Q. And Ethicon would bring in dinner at
12 your practice group's monthly meeting, correct?

13 A. Yes.

14 Q. Turn to page 2.

15 A. (Witness complies.)

16 Q. Does this refresh your recollection of
17 what Carleo's is?

18 MR. MORIARTY: Objection. Unless this
19 was an attachment to the email, it shouldn't be
20 part of Exhibit 17.

21 MR. JONES: Okay. We'll make it
22 Exhibit 17B.

23 (Whereupon Exhibit 17B was marked as an
24 exhibit.)

1 THE WITNESS: Honestly, I -- I -- I
2 don't know where Carleo's is.

3 BY MR. JONES:

4 Q. Okay. But you've been there, though,
5 correct?

6 A. I don't remember going to Carleo's. I
7 don't remember the nightclub.

8 Q. Okay. It says, "Carleo's lounge and
9 nightclub can be perfectly summed up with where
10 southern elegance meets New York decadence."

11 Did I read that correctly?

12 A. That's their motto, it looks like.

13 Q. Okay. And according to Jason Martin,
14 your Ethicon sales rep, you met him in 2011 at
15 Carleo's, correct?

16 A. I might have been there and he was
17 there and we bumped into each other. But I don't
18 remember going to Carleo's. We very rarely go
19 downtown and go to the nightclubs.

20 Q. Okay.

21 A. It's too far away.

22 Q. You can put that away.

23 (Whereupon Exhibit 18 was marked as an
24 exhibit.)

1 BY MR. JONES:

2 Q. Exhibit 18. Exhibit 18 is a 2013
3 Ethicon email, correct?

4 A. Let's see. From Jason, yeah.

5 Q. Correct?

6 A. Yes.

7 Q. Okay. And Jason Martin writes the
8 email part in 2013, correct?

9 A. Yes.

10 Q. Okay. Jason Martin is at this point in
11 time your Ethicon sales representative, correct?

12 MR. MORIARTY: Are you talking about in
13 2013?

14 BY MR. JONES:

15 Q. Jason Martin was your Ethicon sales
16 representative, correct?

17 A. Well, at the time I wasn't using
18 Ethicon products. So he was "the" Ethicon rep; I
19 wouldn't say "my" Ethicon rep.

20 Q. In 2013, you weren't using any Ethicon
21 mesh products, correct?

22 A. No.

23 Q. Correct? That is correct?

24 A. I was not using Ethicon mesh products

1 in 2013.

2 Q. Okay. You were not using Ethicon mesh
3 products in 2014, correct?

4 A. Correct.

5 Q. You were not using Ethicon mesh
6 products in 2015, correct?

7 A. Correct.

8 Q. You're not using Ethicon mesh products
9 in 2016, correct?

10 A. Not yet.

11 Q. The only reason why you're considering
12 using Ethicon mesh products in 2016 is because
13 Astora or AMS has ceased selling the AMS
14 MiniArc-Precise, correct?

15 A. Correct.

16 Q. In 2012, you stopped using Ethicon mesh
17 products, correct?

18 A. After they ran out of TVT-Secur, I used
19 TVT-O and TVT Abbrevio for a period of time, and I
20 don't know if that was on into -- early 2013 or
21 not. But pretty close after that.

22 Q. And Jason Martin writes in this 2000
23 [verbatim] email, "As you both know, Ramsey is a
24 busy surgeon. According to Mike Lewis, he does

1 more prostatectomies than anyone in the
2 country. . . Hello," exclamation point.

3 Did I read that correctly?

4 A. You did.

5 Q. You're a busy surgeon, correct?

6 A. Correct.

7 Q. And you -- have you done more
8 prostatectomies than anyone in the country?

9 A. No.

10 Q. No. More prostatectomies with the
11 da Vinci robot --

12 A. No.

13 Q. -- than anyone else in the country?

14 Do you advertise the use of the
15 da Vinci robot on your practice group's website?

16 A. I wouldn't call it "advertising."

17 Q. You wouldn't call your website -- your
18 listing -- strike that.

19 You wouldn't refer to your content on
20 your practice group's website related to the
21 da Vinci robot system as "advertising"?

22 A. No, I wouldn't.

23 MR. MORIARTY: Objection. Form.

24 THE WITNESS: I wouldn't call it

1 "advertising." I call it information.

2 BY MR. JONES:

3 Q. Okay. You'd call the content on your
4 website related to the da Vinci robot
5 "information"?

6 A. Yes.

7 Q. You wouldn't call it "advertising"?

8 A. No, I wouldn't call it "advertising."
9 I would call it information on what I provide --

10 Q. Would you call --

11 A. -- on my group website. It's not a --
12 it's not a website that we -- that's paid to -- to,
13 you know, be out on -- on TV and ads and -- it's
14 just a resource for patients to look at if they
15 look me up.

16 Q. Okay.

17 A. So they have to -- they have to look
18 for me, as opposed to -- the way I look at
19 advertising is, advertising is looking for
20 patients.

21 Q. Okay. They look you up. They find
22 you. They go to your website, and then they get
23 the content about the da Vinci robot system,
24 correct?

1 A. There's some information on the
2 da Vinci on there.

3 Q. And do you consider the information you
4 have on your website related to the da Vinci robot
5 system as marketing information?

6 A. Again, I don't consider it necessarily
7 marketing or advertisement. It's not something I'm
8 actively putting out there to enhance my name.

9 Q. Okay. But you do list information
10 about the da Vinci robot system when a patient
11 accesses your profile, correct?

12 A. Correct.

13 Q. Do you share information with patients
14 that access your website profile about any medical
15 device other than the da Vinci robot system?

16 A. I think there's information on there
17 about all the separate procedures that I do, and
18 female incontinence is in there as well.

19 Q. On your website?

20 A. I believe so. I haven't looked at my
21 website in a while. It should list things that
22 I -- under my profile, the type of procedures that
23 I do and I offer.

24 Q. Okay. Does it list areas --

1 A. If not, I'll change it.

2 Q. Does it list areas of -- of your --
3 that you specialize in?

4 A. It -- I think all the things that I do
5 surgery in is -- are the things that I specialize
6 in.

7 Q. Does it list areas of special
8 concentration and emphasis of your clinical
9 practice?

10 A. I think the only thing that I -- well,
11 yeah, it's all of them. Everything -- the list of
12 things that I do are things that I concentrate on,
13 I do.

14 More people in my practice are
15 interested in the robots, so there may be more
16 information about that.

17 Q. This email in 2013 marked as
18 Exhibit 18, does it indicate that Ethicon is going
19 to visit your practice?

20 A. He's coming to watch a surgery that I'm
21 doing; so he's coming to the hospital.

22 Q. Okay. And this is Ethicon's sales rep
23 that's going to come visit you at the hospital,
24 correct?

1 A. Yes.

2 Q. Turn to page 2. Who is Mandy Coffman?

3 A. She's my scheduler.

4 Q. Okay. She writes -- she's writing to
5 Jason Martin, your Ethicon sales rep, correct?

6 A. Uh-huh. Yes.

7 Q. She writes, "Good morning, Jason. I
8 hope the boys are well."

9 Did I read that correctly?

10 A. Yes.

11 Q. So she's referring, I assume, to Jason
12 Martin's sons; is that correct?

13 A. In a urology practice, you don't know
14 what "the boys" are.

15 Q. Okay. And then she lists your surgery
16 schedule, correct?

17 A. Yes, for a couple of days. Yeah.

18 Q. And she provides your surgery schedule
19 for the next two weeks to the Ethicon sales rep,
20 correct?

21 A. Yes.

22 Q. And that's so that the Ethicon sales
23 rep can come by and visit you at the hospital,
24 correct?

1 A. Correct.

2 Q. In 2013, correct?

3 A. Correct.

4 Q. How often did -- was an Ethicon sales
5 rep -- strike that.

6 How often did you have contact with the
7 Ethicon sales rep in 2013?

8 A. Not very often. Not specifically
9 for -- I mean, I knew Jason personally, but for --
10 specifically for a -- professionally, I didn't see
11 them very often.

12 Q. Okay. How often personally did you see
13 Mr. Martin?

14 A. Oh, maybe at a football game, maybe at
15 a get-together with friends.

16 Q. Okay.

17 A. He's not what I would consider one of
18 my close personal friends. He's a good friend, but
19 he's not a close personal friend.

20 Q. Fair to say that in 2013, Ethicon sales
21 representatives were exchanging emails with your
22 office about your surgery schedule, correct?

23 A. Not usually. It's not -- it wasn't a
24 common thing at the time. But they did.

1 Q. In Exhibit 18, your staff at your
2 clinic is exchanging emails with Ethicon sales reps
3 about your surgery schedule, correct?

4 A. Yes.

5 Q. You can put that away.

6 MR. MORIARTY: We've been going about
7 an hour and a half. Is this a good time for a
8 break?

9 MR. JONES: Yeah. Let's take a quick
10 break.

11 (Brief recess.)

12 BY MR. JONES:

13 Q. All right. Doctor, after a short
14 break, are you ready to proceed?

15 A. Yes.

16 (Whereupon Exhibit 19 was marked as an
17 exhibit.)

18 BY MR. JONES:

19 Q. Okay. I've handed you Exhibit 19.
20 Exhibit 19 is dated August 2006, correct?

21 A. Yes.

22 Q. And the subject line is "Secur Cadaver
23 Lab, August 11th, Updated Information," correct?

24 A. Yes.

1 Q. And the email is from Susie Chilcoat,
2 correct?

3 A. Yes.

4 Q. She writes, "Hi, all. I just received
5 the arrival/departure information from J&J Travel."

6 Did I read that correctly?

7 A. Excuse me. Where is that?

8 Q. First sentence, first page.

9 A. Yes. Yep.

10 Q. And then she lists underneath that what
11 appears to be dates and times of flights.

12 A. Okay.

13 Q. And if you go about halfway down,
14 you'll see your name --

15 A. Yes.

16 Q. -- Christopher Ramsey, is listed; is
17 that correct?

18 A. Yes.

19 Q. And with a date of August 10th, 2006,
20 correct?

21 A. Yes.

22 Q. Does this indicate that in August 2006
23 you attended a TTV-Secur cadaver lab?

24 A. It looks like that was what it's

1 referring to.

2 Q. Okay. And it looked like -- looks like
3 from -- according to this document, your airfare
4 was out of Knoxville to Atlanta, correct?

5 A. Yes.

6 Q. And then on to Orlando, correct?

7 A. If that's MCO.

8 Q. Okay. Turn to the second page. She
9 writes, "Pick up at hotel, take to Celebration
10 Health Center. Bus will wait."

11 Did I read that correctly?

12 A. Yes.

13 Q. So it indicates that this event in 2006
14 was in Celebration, Florida, correct?

15 A. Correct.

16 Q. And Ethicon would have a car ready to
17 pick you up at the airport, correct?

18 A. Correct.

19 Q. And then, if you look at the bottom of
20 page 2 --

21 A. Mine's different than yours. Okay.

22 Q. If you look at the bottom of page 2,
23 now that we're on the same page together --

24 A. Yes.

1 Q. -- she writes, "Wanted to give you some
2 additional information on the upcoming Secur
3 cadaver lab at Celebration Health on Friday,
4 August 11th. I'm attaching below the hotel
5 confirmation numbers. Please be sure to check
6 in -- please check to be sure you and your doctors
7 have a room."

8 Did I read that correctly?

9 A. Yes.

10 Q. And on page 3 it appears that there's a
11 dinner at Old Hickory Steakhouse in the Gaylord
12 Palms.

13 Did I read that correctly?

14 A. Yes.

15 Q. Yeah. And the hotel is -- let's go off
16 the record real quick.

17 (Brief recess.)

18 (Mr. Orent joins the deposition.)

19 BY MR. JONES:

20 Q. Okay, Doctor, we're looking at
21 Exhibit 18, which is a 2006 email discussing the
22 TVT-Secur cadaver lab in Celebration, Florida,
23 correct?

24 A. Yes.

1 Q. Okay. And it's discussing a dinner at
2 the Old Hickory Steakhouse in the Gaylord Palms,
3 correct?

4 A. Yes.

5 Q. And the hotel listed for this event is
6 the Gaylord Palms in Kissimmee, Florida, correct?

7 A. Yes.

8 Q. And then, underneath that, she writes,
9 "If your doctor has booked their airline tickets
10 through J&J Travel, limo arrangements have been
11 made for them through Concord Limo."

12 Did I read that correctly?

13 A. Yes.

14 Q. And that indicates that Johnson &
15 Johnson has set up limo arrangements to provide
16 transportation for the consultant physicians from
17 the airport to the hotel, correct?

18 A. Yes.

19 Q. And then she writes, "Please have your
20 doctors meet in the lobby and be transported to
21 Celebration Health by bus."

22 Did I read that correctly?

23 A. Yes.

24 Q. And you'll see below this that there's

1 a list of additional names and flight information,
2 correct?

3 A. Yes.

4 Q. Scott Finley is one of the names
5 listed, correct?

6 A. Correct.

7 Q. So that indicates that Mr. Finley was
8 at this event in 2006, correct?

9 A. I don't know if he was at it or not,
10 but he was on this list. So. . .

11 Q. Okay. According to Exhibit 18,
12 Johnson & Johnson had booked airfare for him to be
13 at this event in 2006, correct?

14 A. Correct.

15 Q. Okay. And Mr. Finley you know as an
16 Ethicon sales representative and Ethicon division
17 manager, correct?

18 A. Yes.

19 Q. And then, if you continue to go down
20 that list, you'll see your name, Chris Ramsey,
21 listed, correct?

22 A. Correct.

23 Q. Who is Bob Zipfel?

24 A. I have no idea.

1 Q. You don't know who Robert Zipfel is?

2 A. No.

3 Q. Okay. You can put Exhibit 18 away,

4 Doctor.

5 Exhibit 19 is a 2007 Ethicon email,

6 correct?

7 MR. MORIARTY: Before you go any

8 further, shouldn't this be 20?

9 MR. JONES: Good work. Exhibit 20.

10 Thank you.

11 (Whereupon Exhibit 20 was marked as an

12 exhibit.)

13 BY MR. JONES:

14 Q. Exhibit 20 we'll mark for the record,

15 is a January 2007 email, correct?

16 A. Yes.

17 Q. Okay. And it reads in part, "Today,

18 however, I got a call from an administrative

19 assistant in Dr. Chris Ramsey's office asking how

20 she can return the model since the doctor doesn't

21 want it. I wasn't really sure what to tell her, so

22 I've taken her contact information and told her I

23 would get back to her after I contacted you."

24 Did I read that correctly?

1 A. Yes.

2 Q. Okay. Why did you not want the
3 TVT-Secur device model that Ethicon sent your
4 office?

5 A. I do remember this thing. It was
6 gigantic. It was very realistic and -- and
7 cumbersome, and there's no way I could take it
8 around with me.

9 So I -- they had smaller models that I
10 had used in the past that you could hold in your
11 lap. And this thing was enormous.

12 So I really didn't want to use it in my
13 proctoring. I liked their other, smaller models
14 that they had.

15 Q. Okay. It's fair to say that in 2007
16 and -- sometime in 2006 or 2007, Ethicon sent you a
17 model to be used in TVT-Secur training activities,
18 correct?

19 A. Correct.

20 Q. And the model they sent you was not
21 adequate or too cumbersome for you to use in your
22 TVT training activities?

23 A. It was too adequate.

24 Q. Too adequate?

1 A. Too adequate.

2 Q. You didn't want it, though --

3 A. I didn't want it.

4 Q. -- because it was too adequate?

5 A. Big. It was like a female pelvis, is
6 what it was.

7 Q. It was a female pelvis?

8 A. (Witness moves head up and down.)

9 Q. Okay. Exhibit 21.

10 (Whereupon Exhibit 21 was marked as an
11 exhibit.)

12 BY MR. JONES:

13 Q. I'm not going to spend too much time on
14 this one. Exhibit 21 is a performance and
15 development plan summary final review for Scott
16 Finley for the year 2006.

17 A. Okay. There's a lot of information on
18 this. What are you looking specifically for?

19 Q. I'll direct you.

20 Page 2. It reads, "Brought on two
21 new" -- "Brought on board two new preceptors:
22 Ramsey, TVT, McCauley."

23 Did I read that correctly?

24 A. Yes.

1 Q. And then under "Management Comments,"
2 it reads "Booth captain at AUA."

3 Did I read that correctly?

4 A. Where is that?

5 Yes. Okay.

6 Q. And what does a booth captain at AUA
7 mean to you?

8 A. I don't know what a booth captain is.
9 He might have been at the AUA in 2006.

10 Q. When you went to the AUA convention,
11 were Ethicon employees there?

12 A. Last year? Yes, there were.

13 Q. Did you interact with them there?

14 A. Ethicon? I did not.

15 Q. Which company representatives did you
16 interact with at AUA?

17 A. Intuitive, Medtronic, Dorner, AmnioFix.
18 The -- there's a MRI fusion-guided transrectal
19 biopsy device that's available that I saw.

20 I went to most of the booths in
21 there --

22 Q. Okay.

23 A. -- but those are the ones specifically
24 that I remember.

1 Q. You go out to dinner with employees
2 from those companies?

3 A. I had a -- I had a lunch with
4 Intuitive.

5 Q. Intuitive, you're a consultant for,
6 correct?

7 A. Right.

8 Q. Intuitive took you out to lunch while
9 you were at AUA, correct?

10 A. And Medtronic.

11 Q. Medtronic -- Medtronic and Intuitive
12 took you to lunch when you were at AUA?

13 A. And we had a dinner with AmnioFix and a
14 presentation with AmnioFix.

15 Q. Fair to say that multiple medical
16 device companies were present at AUA, correct?

17 A. Yes.

18 Q. Multiple medical device companies
19 interacted with you at AUA, correct?

20 A. Yes.

21 Q. Multiple medical device companies took
22 you out for meals at AUA, correct?

23 A. Those were associated with
24 presentations.

1 Q. Okay. Multiple medical device
2 companies took you out for meals associated with
3 presentations at AUA, correct?

4 A. Yes.

5 Q. Did Scott Finley bring you on board as
6 an Ethicon preceptor?

7 A. I can't remember if it was Scott Finley
8 or his predecessor that did that. But I don't
9 remember.

10 Q. Who was his predecessor?

11 A. I don't remember that either. I know
12 Todd Kelly was a -- was a representative for Scott,
13 but I don't know if there was someone in between or
14 not. I don't remember who brought me on.

15 MR. JONES: Let's mark Exhibit 22.

16 (Whereupon Exhibit 22 was marked as an
17 exhibit.)

18 BY MR. JONES:

19 Q. Exhibit 22 is a 2007 Ethicon email,
20 correct?

21 A. Yes.

22 Q. And it's an email between Michael Lewis
23 and Scott Finley, correct?

24 A. Looks like it.

1 Q. And you know Michael Lewis and Scott
2 Finley in their roles as Ethicon sales
3 representatives, correct?

4 A. Yes.

5 Q. And Scott Finley emails Mike Lewis in
6 2007 and attaches a sample request form, correct?

7 A. Yes.

8 Q. And if you look at the attachment --

9 A. What did you say? Sample request form?
10 It says "Event Request Form."

11 Q. Event request form, sorry. Scott
12 Finley attaches an event request form to this 2007
13 email, correct?

14 A. Okay. Yes.

15 Q. And if we look at the attachment, it's
16 entitled as "Event Request Form," correct?

17 A. Yes.

18 Q. "Date submitted: August 14th, 2007,"
19 correct?

20 A. Yes.

21 Q. "Product Platform: TVT-Secur,"
22 correct?

23 A. Yes.

24 Q. "Name of requested preceptor: Chris

1 Ramsey," correct?

2 A. Yes.

3 Q. And then it reads, "Business case,
4 including targeted accounts," correct?

5 A. Yes.

6 Q. What does it mean when it states
7 "Business case, including targeted accounts"?

8 A. I don't know, honestly. Doesn't even
9 describe what he's talking about there. I don't
10 know.

11 Q. Did you ever target other doctors for
12 Ethicon in your roll as a consultant physician for
13 them?

14 MR. MORIARTY: Objection.

15 THE WITNESS: No, I didn't target
16 anybody.

17 BY MR. JONES:

18 Q. Does this indicate that in 2007 Ethicon
19 would fill out event request forms for you to
20 provide services related to the TVT-Secur device?

21 A. I'm not sure what they did to do that.
22 But it looks like that's what -- that's what
23 happened there.

24 Q. Okay. Was an Ethicon sales

1 representative present at the Ethicon proctor
2 events you did?

3 A. Most likely.

4 Q. Okay. So every time you did a
5 consulting activity for Ethicon, an Ethicon sales
6 representative was present, correct?

7 A. They may not have been there with a
8 observation. With the proctoring, they would be
9 there.

10 Q. Every proctor event you did for
11 Ethicon, an Ethicon sales representative was
12 present, correct?

13 A. That's right.

14 Q. Can the mesh used in the TVT line of
15 products be a cause of chronic pain?

16 MR. MORIARTY: Objection. Form.

17 Go ahead.

18 THE WITNESS: I don't think the mesh is
19 the cause of the chronic pain.

20 BY MR. JONES:

21 Q. Can it be a cause of chronic pain?

22 A. I don't think the mesh is a cause of
23 chronic pain.

24 Q. Can it ever be a cause of chronic pain?

1 A. I don't think it is.

2 Q. Okay. Mesh -- the mesh used in the TVT
3 line of products in your opinion can never be a
4 cause of chronic pain in women, correct?

5 A. I don't believe the mesh is the cause
6 of chronic pain in women.

7 Q. And the mesh used in the TVT line of
8 products in your opinion can never be the cause of
9 chronic pain in women, correct?

10 A. It's not the cause of chronic pain.

11 Q. Okay. The mesh used in the TVT line of
12 products in your opinion cannot be a cause of
13 dyspareunia, correct?

14 A. I don't think that the mesh is a cause
15 of dyspareunia.

16 Q. Never, correct?

17 A. I've never seen it.

18 Q. Ever?

19 A. I have not, not in my clinical
20 practice.

21 Q. You've never read about it either, have
22 you?

23 A. I've read about it in certain articles
24 that suggest it, but I don't -- I don't think

1 that's the case.

2 Q. Okay. You've read in medical journal
3 articles that the mesh used in the TVT line of
4 products can be a cause of dyspareunia, correct?

5 A. In some articles they suggest that it
6 can be.

7 Q. You disagreed with those articles,
8 correct?

9 A. Yes.

10 Q. Okay. And can the mesh used in the TVT
11 line of products be a cause of discomfort for
12 women?

13 A. Yes, it can be.

14 Q. Okay. Can the mesh used in the TVT
15 line of products cause irritation to women's
16 vaginal tissues?

17 A. With an exposure, there can be some
18 irritation.

19 Q. When the mesh used in the TVT line of
20 products is exposed, it can cause irritation to
21 women, correct?

22 A. Correct.

23 Q. It can cause discomfort to women,
24 correct?

1 A. Correct.

2 Q. It can cause pain to women, correct?

3 A. With exposure.

4 Q. It can cause dyspareunia for women,
5 correct?

6 A. It -- it -- very rarely.

7 Q. But it can, correct?

8 A. It potentially can.

9 Q. It can also cause injuries to the
10 woman's sexual partner, correct?

11 A. Yes.

12 Q. Does the inflammatory response to the
13 mesh used in the TVT products ever stop after the
14 mesh is implanted inside the woman?

15 A. I think, after a certain time, the body
16 doesn't react to the mesh anymore once it's
17 incorporated itself into -- incorporated the mesh
18 into itself.

19 Q. After -- oh.

20 Do you have any idea of when the mesh
21 incorporates into the tissue in a woman?

22 A. I don't know for certain. It's around
23 three to six months.

24 Q. After three to six months, the body

1 stops reacting to the mesh inside of it, correct?

2 A. I believe so.

3 Q. After three to six months, the body no
4 longer has a foreign body reaction to the mesh,
5 correct?

6 A. Correct.

7 Q. What are you relying on to support
8 those opinions?

9 A. Mostly my own clinical experience in
10 seeing patients after -- after surgery and
11 following up long term. But I've seen -- and
12 that's the main thing.

13 Q. And you've already stated that you
14 don't -- you've not created a patient registry for
15 your TVT patients, correct?

16 A. Correct.

17 Q. And you don't report your mesh
18 complications to anyone, correct?

19 A. I have not.

20 MR. JONES: I'll mark Exhibit 23.

21 (Whereupon Exhibit 23 was marked as an
22 exhibit.)

23 BY MR. JONES:

24 Q. The only thing I'm going to ask about

1 Exhibit 23 is, does this indicate that on
2 October 26th, Friday, 2007, that you did a
3 TVT-Secur course for Ethicon?

4 A. I would say I did a proctoring event
5 there.

6 Q. Okay. Well, "List of Courses" and
7 "Course Captain" is what's listed in this email,
8 correct?

9 A. Yes.

10 Q. And it's written by Scott Finley,
11 correct?

12 A. Yes.

13 Q. He's division manager, correct?

14 A. Yes.

15 Q. And he writes, "Courses and course
16 captains," correct?

17 A. Correct.

18 Q. And for -- for courses and course
19 captains, he lists "Chris Ramsey and Mike Lewis,
20 October 26th, 2007," correct?

21 A. Correct. This looks more like probably
22 what I would do as an observation. I would have a
23 couple of surgeons come in and watch me do a case,
24 is probably what this was.

1 Q. And Ethicon would pay you for that,
2 correct?

3 A. Correct.

4 Q. And those would be surgeries that you
5 would also bill the patient for, correct?

6 A. Correct.

7 Q. So you would be paid by Ethicon for
8 those surgeries to observe, correct?

9 A. I would be paid by Ethicon to explain
10 what I was doing to several surgeons in the middle
11 of my case.

12 Q. Okay. With an Ethicon sales rep
13 present, correct?

14 A. Typically.

15 Q. Well, here we know he was present,
16 correct?

17 A. We don't know he was present. He
18 was --

19 Q. He's listed as a course captain,
20 correct?

21 A. Right.

22 Q. So here we know at this occasion, Mike
23 Lewis, your Ethicon sales rep, was listed as a
24 course captain, correct?

1 A. Yes.

2 Q. Okay. And Ethicon would pay you --
3 when they came and observed you, Ethicon would pay
4 you for your time that other surgeons observed your
5 procedure, correct?

6 A. Correct.

7 Q. And you would pay Ethicon for the
8 products you used during that time, correct?

9 A. No, I would not pay Ethicon.

10 Q. Ethicon gave you the products for free
11 that you used at these events?

12 A. I've never paid for the products from
13 Ethicon.

14 Q. Ethicon billed you -- billed you for
15 the products you used at these --

16 A. They don't bill me; they bill the
17 hospital.

18 Q. They billed your hospital, correct?

19 A. Correct.

20 Q. Okay. You didn't get these free of
21 charge; your hospital didn't get these free of
22 charge, correct?

23 A. I don't know about that. I know I have
24 gotten some free of charge in the past. I don't

1 know if these were given free or charge of not.

2 Q. Ethicon has given you slings free of
3 charge in the past?

4 A. When I've -- when I first started
5 using, I think that they were allowing me to use it
6 at first for several surgeries to make sure that I
7 liked it and that I wanted to continue to use it.

8 I think so. I don't remember that,
9 honestly. But I think so.

10 Q. Subject line of this email is "Prof ed
11 courses and spending."

12 A. Okay.

13 Q. Did any of your sales reps ever
14 communicate to you budget concerns with the Ethicon
15 professional education program?

16 A. No.

17 Q. Never?

18 A. No.

19 Q. Never in an email?

20 A. I -- I don't remember.

21 Q. Okay.

22 A. It wasn't their typical policy to talk
23 to me about what was going on in their -- within
24 their inner workings.

1 MR. JONES: Okay. Let's mark
2 Exhibit 23.

3 (Whereupon Exhibit 24 was marked as an
4 exhibit.)

5 MR. MORIARTY: 24.

6 MR. JONES: Thank you, Counselor.

7 MR. MORIARTY: That's all I'm good for,
8 is occasional numeric sequence.

9 MR. JONES: You're good at it, though.
10 Thank you, though. I do appreciate it.

11 BY MR. JONES:

12 Q. Okay. Exhibit 24. I want to read
13 middle of the email -- October 26th.
14 "October 26th, TVT-Secur, Chris Ramsey, Knoxville.
15 Dr. Ramsey is a urologist who will help with any
16 urology customers that you may have, including
17 dinner programs."

18 Did I read that correctly?

19 A. Yes.

20 Q. And this is a 2007 Ethicon email
21 drafted by Scott Finley, correct?

22 A. Correct.

23 Q. Scott Finley was division manager and
24 Ethicon sales rep for you, correct?

1 A. Correct.

2 Q. Okay. And does this indicate that his
3 impression was that you would do dinner programs
4 for Ethicon?

5 A. Yes. Usually I would just be meeting
6 with them at dinner and discussing the products. I
7 didn't have a formal presentation arrangement.

8 Q. You met with Ethicon employees for
9 dinner to discuss the TVT-Secur device, correct?

10 A. Yes.

11 Q. How many times?

12 A. I have no idea how many times.

13 Q. Ethicon pay for those dinners?

14 A. Yes.

15 Q. Every time?

16 A. Yes.

17 Q. Where did they occur?

18 A. Restaurant.

19 Q. Where?

20 A. I don't recall the restaurants.

21 Q. In Knoxville?

22 A. Yes.

23 Q. Was it always with Chris Finley -- or
24 Scott Finley?

1 A. No, not always with Scott Finley.

2 Q. Who else did you meet with?

3 A. Probably Mike Lewis.

4 Q. Mike Lewis and Scott Finley would take
5 you out to dinner to discuss TVT-Secur, correct?

6 A. Yes.

7 Q. And did you communicate to them that
8 you were willing to help with any urology
9 customers?

10 A. Yes.

11 Q. And this would have been in the 2006 to
12 2011 time frame, correct?

13 A. Probably.

14 Q. So from 2006 to 2011, you told Ethicon
15 you would help out with any urology customers on
16 the TVT-Secur device --

17 (Reporter interruption for
18 clarification.)

19 BY MR. JONES:

20 Q. From 2006 to 2011, you communicated to
21 Ethicon you would help with any urology customers
22 on the TVT-Secur device?

23 A. Correct.

24 Q. And from 2006 to 2011, Ethicon sales

1 representatives and division managers would take
2 you out to dinner to talk about the TVT-Secur
3 device, correct?

4 A. Occasionally.

5 Q. You can put that one away.

6 Do you know who Dr. Jeffrey Dale is?

7 A. Dale or Dell?

8 Q. Dell.

9 A. Dell. Yes.

10 Q. Okay. Who is he?

11 A. He's a urogynecologist in Knoxville.

12 Q. Do you refer patients to Dr. Dell?

13 A. No.

14 Q. Have you ever?

15 A. Not that I recall. May have one or
16 two, but I sure don't do it very often.

17 Q. Okay. Is Dr. Dell an Ethicon
18 consultant as well?

19 A. I'm not aware of it.

20 Q. Do you have any interactions with
21 Dr. Dell?

22 A. Pass him in the hall. Physician's
23 lounges. We're cordial.

24 Q. In your role as a consultant for

1 Ethicon, did you consider yourself a business
2 partner with Ethicon?

3 MR. MORIARTY: Objection. Asked and
4 answered yesterday.

5 THE WITNESS: I don't think that I
6 consider myself a business partner.

7 MR. JONES: I'll mark the next
8 exhibit 25.

9 (Whereupon Exhibit 25 was marked as an
10 exhibit.)

11 BY MR. JONES:

12 Q. Turn you to page 2, the bottom of
13 page 2 of Exhibit 25.

14 This is a 2007 Ethicon email, correct?

15 A. Yes.

16 Q. The subject line is "Health care
17 compliance training requirements for preceptors,"
18 correct?

19 A. Yes.

20 Q. And it says, "Dear Health Care
21 Providers, Ethicon, Incorporated, has developed a
22 health care compliance training course and
23 certification for business partners who interact
24 with health care professionals on our behalf."

1 Did I read that correctly?

2 A. Yes.

3 Q. "As a professional contracted to train
4 or speak to other health care professionals on
5 Ethicon's behalf, you have been identified as a key
6 individual who must complete health care training
7 compliance" -- "health care compliance training."

8 Did I read that correct?

9 A. Yes.

10 Q. And did you complete this health care
11 compliance training?

12 A. I don't remember if I did or didn't. I
13 may have.

14 Q. Okay. If it was required per your
15 contract, you would have completed it, correct?

16 A. Yes.

17 Q. "As per your contract terms, you have
18 agreed to participate in such training scheduled by
19 the company."

20 Did I read that correctly?

21 A. Is that still on the first page?

22 Yeah.

23 Q. Yes, I did?

24 A. Yes. That's what it says there.

1 Q. And this is Ethicon communicating that
2 you as a consultant is a business partner of
3 Ethicon, correct?

4 A. That's what they're saying.

5 Q. Do you disagree with that?

6 A. I don't consider myself a partner of
7 theirs.

8 Q. But you understand that Ethicon
9 considered you a business partner of theirs in your
10 role as a consultant?

11 A. I don't --

12 MR. MORIARTY: Objection.

13 Go ahead.

14 THE WITNESS: I don't know if they
15 considered me a business partner. That's the terms
16 that they used.

17 BY MR. JONES:

18 Q. The term they used inside the company
19 was that you were a business partner, correct?

20 A. That's the term that they use. I
21 consider myself a consultant.

22 Q. Now, this email where they've described
23 you as a business partner eventually gets emailed
24 to you, correct?

1 A. I don't know -- does it? Is that on
2 there?

3 Yes, they have my name there.

4 Q. Okay. So you received this email,
5 correct?

6 A. I don't know if I received it or not.

7 Q. Your email address is listed as a
8 recipient of this email, correct?

9 A. My name is. It doesn't have the email
10 address.

11 Q. Okay. "Chris Ramsey M.D. email,"
12 correct?

13 A. That's what it says.

14 Q. Okay. Along with other physicians that
15 are listed as recipients, correct?

16 A. Correct.

17 Q. And it writes, "Dear Preceptor" -- and
18 this is from Bob Zipfel, correct?

19 A. Yes.

20 Q. He writes "Dear Preceptor," correct?

21 A. Yes.

22 Q. You were a preceptor, correct?

23 A. I was.

24 Q. During this time period, correct?

1 A. Yes.

2 Q. Okay. "Please take note of this very
3 important email sent by Patti Logan on September
4 11. Completion of this quick assessment is
5 required."

6 Did I read that correctly?

7 A. Yes.

8 Q. And so this communication where Ethicon
9 has referred to you as a business partner is then
10 sent out to a list of preceptors, correct?

11 A. Yes.

12 Q. And you're listed in the recipient
13 email line, correct?

14 A. Correct.

15 Q. So according to the email recipient
16 list, you received this email in which Ethicon
17 referred to you as a business partner, correct?

18 A. My name's on it. Again, I don't know
19 if I received it or not.

20 Q. Your name's listed as a recipient of an
21 email where Ethicon referred to you as a business
22 partner of theirs, correct?

23 A. No. That's -- the one that says that
24 is to the Ethicon employees. The one that was sent

1 to me doesn't say that I'm a business partner.

2 Q. Okay. It was in the email below it,
3 correct?

4 A. Right.

5 Q. That was forwarded to you, correct?

6 A. I don't know if -- was that forwarded
7 to me? I don't know if it was forwarded to me or
8 not.

9 Q. You don't know what "FW" means in a
10 subject line?

11 A. But I don't know the -- if this -- if
12 this whole thing was forwarded to me or not. I
13 don't know what was sent to me.

14 Q. Okay. It says "Forward: Health care
15 compliance training requirement for preceptors,"
16 correct?

17 A. Right. But I don't know if everything
18 below this was sent to me or not.

19 Q. And then the email -- I'll represent to
20 you this is how it was produced.

21 A. Okay.

22 Q. And in the email below it, it was
23 included, okay?

24 A. Okay.

1 Q. So in 2007 you're listed as a recipient
2 of an email that includes language that calls you a
3 business partner for Ethicon, correct?

4 A. It looks like it.

5 Q. Okay. We'll move on.

6 (Whereupon Exhibit 26 was marked as an
7 exhibit.)

8 BY MR. JONES:

9 Q. Exhibit 26. And this is a 2000
10 [verbatim] email from Scott Finley, correct?

11 A. From Scott Finley or to?

12 MR. MORIARTY: Do you have an extra?

13 BY MR. JONES:

14 Q. From Scott Finley, correct?

15 A. It looks like it's from Mike Lewis.

16 Q. Yeah. An email between Mike Lewis and
17 Scott Finley in 2007, correct?

18 A. Yes.

19 Q. Discussing TVT-S preceptorships,
20 correct?

21 A. Yes.

22 Q. He writes, "I am working with Fleet and
23 Dave to get a date from Ramsey. They are both
24 saying they have two docs they want to send. We

1 may end up sending Ramsey to Fleet's territory for
2 a proctorship."

3 Did I read that correctly?

4 A. Yes.

5 Q. Does that indicate that Ethicon has two
6 doctors they want to send to you in 2007 to be
7 trained on TVT-S?

8 A. Not to me necessarily. They just have
9 two docs that they want to have trained.

10 Q. Okay. Two doctors are indicating they
11 want training on TVT-Secur?

12 A. Correct.

13 Q. And Ethicon's either going to send you
14 to them or they're going to pay for those doctors
15 to come to you, correct?

16 A. I honestly don't know.

17 Q. They're considering using you in 2007
18 to train these doctors?

19 A. It looks like it.

20 Q. So in 2007, in your role as a
21 consultant physician for Ethicon, you would --
22 Ethicon would pay for you to travel to other
23 surgeons and train them on the TVT-Secur device?

24 A. I did that one time that I remember,

1 going out of town. I don't remember if I did -- I
2 may have done it more, but I don't remember. I
3 remember one going up to Kentucky once.

4 Q. Ethicon would pay for surgeons in 2007
5 to travel to you to watch you perform the TVT-S
6 procedure, correct?

7 A. I don't think they paid them. I think
8 they paid their way. I don't think they actually
9 paid them a fee to come watch me.

10 Q. Ethicon paid for their travel for
11 them --

12 A. Probably.

13 Q. Okay.

14 -- to be trained by you on TVT-Secur,
15 correct?

16 A. Probably. I don't know what they did
17 with the people that came to see me.

18 MR. JONES: You can put that away.

19 Okay. Let's mark Exhibit 27.

20 (Whereupon Exhibit 27 was marked as an
21 exhibit.)

22 BY MR. JONES:

23 Q. I'm just going to ask you questions
24 about the bottom of page 1, where it says "Ramsey,"

1 and about the title of the document.

2 Exhibit 27 is a field visit letter,
3 correct?

4 A. Yes.

5 Q. Exhibit 27 is a field visit letter with
6 a sales rep named Mike Lewis, correct?

7 A. Yes.

8 Q. Division manager Scott Finley, correct?

9 A. Yes.

10 Q. And January 2008 is the field visit
11 date, correct?

12 A. Okay.

13 Q. And at the bottom of page 1, under the
14 heading "Negative Trend," the second bullet point
15 reads, "TVT is on a negative trend due to volume
16 issues."

17 Did I read that correctly?

18 A. Yes.

19 Q. "TVT is on a negative trend due to
20 volume issues, economic factors listed above, and
21 competitive issues."

22 Correct?

23 A. Okay.

24 Q. "This product line needs a great deal

1 of focus in Quarter 1 and Quarter 2 of 2008 to get
2 it moving forward."

3 Did I read that correctly?

4 A. Yes.

5 Q. Now, Mike Lewis is your Ethicon sales
6 rep, correct?

7 A. At that time, yes.

8 Q. "Plan: Conduct effective field
9 marketing programs with busy users and convert the
10 two or three competitive sling users that exist in
11 your territory."

12 Did I read that correctly?

13 A. Yes.

14 Q. "You will need to focus on your key
15 users to defend your business and drive growth from
16 these very busy surgeons, i.e., Ramsey, Dell,
17 Nicely, Parker, Cameron, Bell, Hartline, Morgan,
18 and Ruby."

19 Did I read that correctly?

20 A. Brown, not --

21 Q. Brown. Okay.

22 Were you a key user in 2008 of the
23 TVT-Secur device?

24 A. I don't know if I was a key user. I

1 was a busy user.

2 Q. You were a very busy user of the
3 TVT-Secur device, correct?

4 A. Again, I don't know what qualification
5 for that, busy, but --

6 Q. According to your sales representative,
7 you were a key user and a very busy user of the
8 TVT-Secur device in 2008, correct?

9 A. Including several other people.

10 Q. Several other people, including some of
11 which are your partners, correct?

12 A. Correct.

13 Q. Which ones listed here are your
14 partners?

15 A. Nicely, Parker, and Cameron.

16 Q. Four of these surgeons listed on
17 Exhibit 27 as key users and very busy surgeons of
18 the TVT-Secur device are part of your practice
19 group, correct?

20 A. Yes.

21 Q. In 2008 did you increase your use of
22 TVT-Secur?

23 A. I have no idea how -- how much -- you
24 know, what my volume was.

1 Q. Do you recall there being a negative
2 trend with the use of TVT products in 2008?

3 MR. MORIARTY: Objection.

4 THE WITNESS: I have no idea about
5 their internal issues. You know, for me, I don't
6 think it was any change. It was business as usual
7 for me.

8 BY MR. JONES:

9 Q. Okay. Did you try to drive growth at
10 all?

11 A. No.

12 Q. Okay. Did you ever feel like Ethicon
13 sales representative Mike Lewis was trying to drive
14 growth of TVT sales?

15 A. He was -- was he trying to drive
16 growth? Not through me. Not by me.

17 Q. We'll put that one away.

18 TVT-Secur device, when did you start
19 using it?

20 A. 2006.

21 Q. When did you stop using it?

22 A. Probably end of 2012, when they ran out
23 of them.

24 Q. And you used it a total of how many

1 times?

2 A. Around 400, is what I think I
3 represented.

4 Q. Okay. And you performed an independent
5 literature search prior to using the TVT-Secur
6 device in 2006, correct?

7 A. There wasn't a whole lot of independent
8 literature on the market at the time, because I was
9 one of the first users in the country to use it.
10 But I did review their studies that they had. I
11 went to their -- their breakout session that showed
12 the information about TVT-Secur, how it worked, how
13 it was put in.

14 Q. Okay. At the -- in 2006, when you
15 first started using this TVT-Secur device, there
16 was not a -- a lot of clinical study data on the
17 product, correct?

18 A. Correct.

19 Q. There was limited clinical study data
20 on TVT-Secur in 2006 when you started using it,
21 correct?

22 A. On the Secur device, yes.

23 Q. Were there any long-term safety studies
24 on the TVT-Secur device in 2006?

1 A. Long-term safety studies? Yes.

2 Q. Which ones?

3 A. The ones that discussed TVT mesh in
4 general.

5 Q. Does the --

6 A. You asked about safety. So --

7 Q. Does the Ulmsten -- or do you know what
8 the Ulmsten 17-year data study is?

9 A. I'm familiar with it.

10 Q. Does that apply to the -- was that done
11 on the -- which product was that done on?

12 A. TVT Retropubic.

13 Q. Does that apply to the TVT Exact
14 device?

15 A. I'm not certain.

16 Q. Does that apply to the TVT Abbrevio
17 device?

18 A. No.

19 Q. Does that apply to the TVT-Secur
20 device?

21 A. No.

22 Q. Does it apply to the TVT Obturator
23 device?

24 A. No.

1 Q. What clinical studies were available in
2 2006 specifically on the TVT-Secur device?

3 A. I can't remember if they -- if some of
4 the original surgeons who helped develop it had
5 studies specific to the TVT-Secur. Honestly, I
6 can't remember what it -- what it showed.

7 Q. There wasn't much, though?

8 A. No, there was -- there wasn't a lot
9 of -- of data. I think there was a couple of
10 implanted -- several -- and, again, I don't know
11 how many -- but many had followed them over a
12 certain period of time. Again, I don't how long it
13 was.

14 Q. Is there a learning curve to the TVT-S
15 device?

16 A. Yes.

17 Q. What is the learning curve?

18 A. It's different for everybody.

19 Q. What is the estimate of the learning
20 curve?

21 A. It's completely different for
22 everybody. There's no way to put a learning curve.
23 It's -- it's really -- depends on your familiarity
24 with the -- with the technique -- with midurethral

1 slings in the first place, with stress urinary
2 incontinence surgeries in the first place, and then
3 your comfort level with using the device.

4 Q. Okay. What was your learning curve
5 with TVT-S?

6 A. I think that I started feeling pretty
7 comfortable with it after about ten -- ten
8 patients.

9 Q. What do you mean, you felt "comfortable
10 with it" after ten patients?

11 MR. MORIARTY: Objection. Form. He
12 said "very comfortable."

13 BY MR. JONES:

14 Q. What do you mean by "very comfortable"?

15 A. There was some issues early on removing
16 the trocar device, the placement device. And that
17 was difficult to -- to get used to at first.

18 I don't think that I really had a whole
19 lot of problem with efficacy. It was just placing
20 the device in a comfortable manner, getting it in
21 the right spot, and then removing the device.

22 Q. Fair to --

23 A. Once I got it figured out, it was just
24 a piece of cake, once I got it figured out.

1 Q. Once you -- fair to say that other
2 surgeons are likely to have a higher learning curve
3 than ten patients?

4 A. Maybe. I can't speak to them.

5 Q. You can't speak to the learning curve
6 for any other physician, correct?

7 A. I think everybody's learning curve is
8 going to be different.

9 Q. So you can't speak to their learning
10 curves?

11 MR. MORIARTY: Objection.

12 THE WITNESS: Some might be faster than
13 me. Some, you know, are slower than me.

14 BY MR. JONES:

15 Q. What was your experience in TVT-Secur
16 proctorships with surgeons who participated in
17 their learning curves?

18 A. I guess I don't know what you mean,
19 what my experience was.

20 Q. The surgeons that you interacted with
21 in these proctors -- proctorships, what was their
22 learning curve --

23 A. Oh, I don't know --

24 Q. -- on TVT-S?

1 A. -- I don't know what their learning
2 curves would have been. I didn't follow up with
3 them unless they had questions to ask me, and I
4 don't remember anybody calling me.

5 Q. When did you first start using the
6 TVT-O device?

7 A. TVT-O? I think around 2004 or 2005.

8 Q. When did you stop using the TVT-O
9 device?

10 A. 2006, when I -- when I started using
11 the TVT-Secur.

12 Q. So you used the TVT-O for about a year
13 or two?

14 A. Probably two, maybe two or three years.

15 Q. How many did you put in?

16 A. Around 300.

17 Q. You put 300 TVT-Os in in two or three
18 years?

19 A. Yeah. Yes.

20 Q. Prior to -- how many TVT Retropubics?

21 A. Not very many. Twenty-five or 50 is
22 what I had represented in my report. That's
23 including residency and into practice.

24 Q. Okay. Take off residency.

1 How many TVT Retropublics?

2 A. Probably 25. Half. Half of that.

3 Q. Half of the TVT Retropublics you placed
4 were during your residency, correct?

5 A. Probably.

6 Q. When did you stop using the TVT
7 Retropubic device?

8 A. I kind of used it on and off throughout
9 the -- after residency. I would use pubovaginal
10 sling with bone anchors probably more than I used
11 the TVT --

12 Q. Okay. When did you stop using the TVT
13 Retropubic device?

14 A. When I started using the TVT-O.

15 Q. So 2004, 2005, correct?

16 A. 2003, 2004, 2005.

17 Q. You've used Abbrevio, correct?

18 A. I have, probably maybe ten times.

19 Q. Ten times, what -- what years?

20 A. End of 2012 and 2013.

21 Q. Did you also do maybe a couple of
22 TVT-Os then?

23 A. Probably, yes.

24 Q. In addition to the 300 that you put in

1 in the two-or-three-year period earlier?

2 A. Sure. You can add that into my
3 total --

4 Q. Okay.

5 A. -- experience.

6 (Reporter interruption for
7 clarification.)

8 BY MR. JONES:

9 Q. Several TVT-Os in 2012 or 2013,
10 correct?

11 A. Yes.

12 Q. By 2005, how many Ethicon mesh products
13 had you put in?

14 A. By '05? Maybe 200, 250.

15 Q. And then, starting in 2012 or 2013, you
16 start using AMS mesh products, correct?

17 A. Just the MiniArc-Precise.

18 Q. You started using it in 2012?

19 A. End of 2012.

20 Q. How many?

21 A. How many of those? Probably 180 or so,
22 180 to 200.

23 Q. Have -- other than the sling products
24 we just discussed, have you implanted any other

1 sling products in women?

2 A. I did -- we did SPARCs in residency as
3 well. I don't think I used any of the Bard or
4 Boston products that I remember. Maybe a couple
5 Monarcs.

6 Q. Is the mesh used in SPARC the same as
7 the mesh as -- used in TVT?

8 A. It's polypropylene mesh. It's very
9 similar.

10 Q. Any difference in the tensioning of the
11 AMS SPARC device with the TVT-O or TVT Retropubic
12 device?

13 A. I tension them the same way.

14 Q. Any difference in the design of the
15 mesh used in AMS SPARC with regards to tensioning?

16 A. No, not with regards to tensioning.

17 Q. Any added product features of the AMS
18 SPARC mesh that help a surgeon tension the AMS
19 SPARC mesh?

20 A. Compared to TVT?

21 Q. Correct.

22 A. I don't think there was any advantage
23 one way or the other.

24 Q. Any differences from --

1 A. From the tensioning, no.

2 Q. Never used the Bard mesh product,
3 correct?

4 A. No.

5 Q. Never used the Boston Scientific mesh
6 product, correct?

7 A. No.

8 Q. Ever use the Boston Scientific Solyx
9 device?

10 A. I don't think so. I don't -- so,
11 again, I don't know which company makes, you know,
12 these -- Solyx does sound familiar. I don't think
13 I've used it. I've looked at it. I don't remember
14 much about it. I don't --

15 Q. Okay. What did you think of the
16 design?

17 A. I don't remember much about it.

18 Q. Okay.

19 A. I really -- I don't think I used it. I
20 can't remember using it.

21 Q. Okay. You've -- and you've never used
22 hernia mesh outside of your residency, correct?

23 A. No.

24 Q. And never used mesh for pelvic organ

1 prolapse, correct?

2 A. No.

3 Q. You used TVT-S from 2006 to 2012 400

4 times, correct?

5 A. Approximately.

6 Q. How many times did you use it in 2006?

7 A. Oh, I have no idea how I broke that

8 down.

9 Q. Haven't broken that down?

10 A. It's fairly similar, probably. You
11 know, it's a six-year period, so, you know,
12 probably 50 to 75 a year or 50 to 100 a year,
13 depending on how busy I was. I know some years I
14 was more busy than others. But it would be between
15 75 to 100 a year.

16 Q. Does it sound right that 2008 would
17 have been the year you used TVT-Secur the most?

18 A. I have -- couldn't tell you.

19 Q. Couldn't tell us?

20 A. Couldn't tell you.

21 Q. Couldn't tell us the exact number of
22 TVT-Securs either --

23 A. No.

24 Q. -- correct?

1 Okay. Same for TVT-O?

2 A. Correct.

3 Q. Couldn't tell us the exact number,
4 correct?

5 A. I couldn't tell you.

6 Q. Can't tell us --

7 A. I couldn't tell you.

8 Q. -- the amount of times that you used it
9 per year?

10 A. No.

11 Q. Okay. And the same for TVT Retropubic,
12 correct?

13 A. Correct.

14 Q. Have you ever attempted to do an
15 analysis of your precise complication rate with TVT
16 Retropubic?

17 MR. MORIARTY: Objection.

18 THE WITNESS: I recently looked at how
19 many revision surgeries that I've done over the
20 last three years, is all I could come up with,
21 compared to my placement surgeries.

22 BY MR. JONES:

23 Q. So that's a no -- correct? -- to my
24 question?

1 A. So the last three years, I did.

2 Q. Well, TVT Retropubic, you haven't put
3 in in the last three years?

4 A. You said Retropubic.

5 Q. Yeah.

6 A. I apologize. I thought you were --

7 Q. Can we read that question back.

8 A. Yeah, please. Thank you.

9 (Whereupon the previously mentioned
10 question was read back by the reporter.)

11 THE WITNESS: Okay. No.

12 MR. JONES: Thanks.

13 BY MR. JONES:

14 Q. Have you ever tried to do a precise --
15 have you ever tried to study or analyze your
16 complication rate with the TVT-O device?

17 A. No.

18 Q. With the TVT-S device?

19 A. No.

20 Q. Outside of the last three years, you
21 have no data related to your revision rates,
22 correct?

23 A. I have no precise data.

24 Q. No data that you can provide me,

1 though, correct?

2 A. I -- I could -- I guess I could look
3 back into my medical records over the last 12 years
4 and probably come up with that, if I -- if I had
5 to, but I don't have that data right now.

6 Q. But you haven't done that, correct?

7 A. No. I don't --

8 Q. And Ethicon hasn't asked you to do
9 that, correct?

10 A. No, sir.

11 Q. Do you know what your loss to follow-up
12 rate is with your transvaginal mesh patients?

13 A. I would say it's fairly -- I mean, as
14 far as loss to follow-up that I had planned on
15 following up in the future, or just I don't see
16 them any more because they don't need to come back
17 to see me?

18 Q. Both.

19 A. Well, I mean, for loss to follow-up,
20 would be pretty low. There are patients who don't
21 come back after surgery because they follow up with
22 their GYNs on their own accord. I always want them
23 to come back. But most patients do come back, and
24 I'm able to follow them for the first several

1 months after surgery.

2 Q. Some patients don't come back?

3 A. Some patients don't. Very few don't.

4 Q. But you don't know your precise rate of
5 how many patients?

6 A. It would be -- it would be less than 10
7 percent that don't follow up.

8 Q. Do you know what the average rate among
9 surgeons is for loss to follow-up rate --

10 A. No -- I don't.

11 Q. -- with transvaginal mesh patients?

12 A. No idea.

13 Q. So when you say it's very low, what are
14 you comparing it to?

15 A. Seems low to me.

16 Q. Seems low to you?

17 A. Yes.

18 Q. But you're not making a comparison
19 to --

20 A. Correct.

21 Q. -- any other known rates, correct?

22 A. Correct.

23 Q. Just something that in your head seems
24 very low, correct?

1 A. Right. Yes, sir.

2 Q. And this is going to be painful, but,
3 so the record's clear, 2006 to 2012, you implanted
4 about 400 TVT-S devices, correct?

5 A. Correct.

6 Q. From 2000- -- from 2003 or 2004 through
7 2006, you implanted 300 TVT-O devices, correct?

8 A. Correct.

9 Q. From 2000 to 2003, you implanted 25 to
10 50 TVT Retropubic devices, correct?

11 A. Correct.

12 Q. In 2012 or 2013, you implanted about 10
13 TVT Abbrevos, correct?

14 A. Correct.

15 Q. And in that same period, you implanted
16 several TVT-O devices, correct?

17 A. Correct.

18 Q. You don't know whether those TVT-O
19 devices were -- used mechanical-cut mesh or
20 laser-cut mesh, correct?

21 A. I think they were probably laser-cut
22 mesh because of the date.

23 Q. That's true.

24 Those -- you believe the TVT-O devices

1 you placed in 2012 or 2013 were laser-cut mesh,
2 correct?

3 A. Probably.

4 Q. In 2012, you started using AMS
5 MiniArc-Precise, correct?

6 A. Correct.

7 Q. From 2012 to today, you've implanted
8 180 AMS MiniArc-Precise --

9 A. Around that, yes.

10 Q. Did you do an independent literature
11 search on AMS MiniArc-Precise before you started
12 using it?

13 A. I looked at the data. I looked at some
14 of the data. The sling was put in very similar to
15 the TVT-Secur, so I felt very comfortable with it.

16 Q. Okay. What are -- do you consider the
17 AMS MiniArc-Precise safer than the TVT-Secur
18 device?

19 A. No.

20 Q. Do you consider the TVT-Secur device
21 safer than the AMS MiniArc device?

22 A. No.

23 Q. Do you consider AMS -- Ethicon --
24 strike that.

1 Do you consider Ethicon transvaginal
2 mesh products safer than AMS transvaginal mesh
3 products?

4 MR. MORIARTY: Objection. Form.

5 Go ahead.

6 THE WITNESS: No.

7 BY MR. JONES:

8 Q. What are the differences between the
9 AMS MiniArc-Precise and the TVT-Secur device?

10 A. As far as the mesh? As far as the
11 instruments to place it? Do you mean how to put it
12 in?

13 Q. Tell me -- start with the mesh.

14 A. Well, the mesh is polypropylene. It's
15 very similar.

16 Q. Just tell me the differences.

17 A. The pore sizes are a little smaller, I
18 believe.

19 Q. Pore size is smaller with AMS?

20 A. A little bit smaller. A little bit
21 smaller.

22 I think the weight is the same. The
23 length is about the same. I'm not sure if the
24 width is exactly the same or not. But there might

1 be a millimeter difference, I'm not sure.

2 Q. Are the fixation principles the same?

3 A. They're different.

4 Q. Okay. Explain the differences between
5 the way you fixate the TVT-Secur device in place
6 compared to the AMS MiniArc-Precise.

7 A. So they're -- they're placed -- in my
8 hands, they're placed the same way. The fixation
9 device in the -- in the MiniArc-Precise uses an
10 absorbable anchor that is put in behind the pubic
11 bone. That's where it receives its initial tension
12 and its support.

13 And in the TVT-Secur it uses what they
14 call a Vicryl fleece jacket. It's also absorbable.
15 It's placed basically in the same place.

16 So their anchoring methods are a little
17 different.

18 Q. Okay. Do those anchoring meth- --
19 strike that.

20 Did the difference in anchoring methods
21 between the AMS MiniArc-Precise and TVT-Secur
22 affect the efficacy of those devices?

23 A. I think they were very similar.

24 Q. Did the difference in anchoring

1 principles affect the safety of those devices?

2 A. No. They're both absorbable.

3 Q. You're familiar with the Cochrane
4 analysis on mini-slings, correct?

5 A. I'm familiar with them.

6 Q. Do you know who Joy de los Reyes is?

7 A. I've met her. I -- I know her, but
8 I -- I haven't spoken to her in years.

9 Q. Okay. You met with her, correct?

10 A. Yes.

11 Q. Where did you meet with her?

12 A. I don't remember. Probably -- maybe at
13 a meeting, maybe.

14 Q. Okay. What does she do at Ethicon?

15 A. I don't know what her job was.

16 (Mr. Orent leaves the deposition.)

17 THE WITNESS: She was just a nice lady
18 that I talked to.

19 BY MR. JONES:

20 Q. She does seem like a nice lady.

21 Do you -- did you ever express to
22 Ethicon your interest in getting more involved in
23 teaching nationally?

24 A. I -- if -- I don't recall a

1 conversation like that. A national teaching? I
2 don't recall that. I've never really had big
3 aspirations, that I can remember, to do that.

4 But, you know, maybe because I -- I
5 thought I did have a fairly unique experience with
6 TVT-Secur that I could help. But I don't honestly
7 recall that.

8 Q. Okay. What is your fairly unique
9 experience with TVT-Secur?

10 A. Well, I thought I had good results with
11 it, better than some of the reported results. I
12 thought that I did it very safely and -- and
13 efficiently. And the things that I could -- that I
14 did, I could probably show other physicians to help
15 them learn how to do it in a more efficient manner
16 to improve their efficacy.

17 Q. Okay. It's fair to say that you felt
18 your results with TVT-Secur were better than what
19 other surgeons were reporting --

20 A. Some other surgeons, yes.

21 Q. And it's fair to say that, among
22 surgeons, there was a concern with the results they
23 were seeing with TVT-Secur, correct?

24 MR. MORIARTY: Objection. Form.

1 Go ahead.

2 THE WITNESS: Some surgeons had had
3 concern with that, yes.

4 BY MR. JONES:

5 Q. And some surgeons after the launch of
6 TVT-Secur were concerned with whether or not they
7 were getting adequate results with their use of
8 TVT-Secur, correct?

9 MR. MORIARTY: Objection. Form.

10 Go ahead.

11 THE WITNESS: Some were concerned with
12 their -- with their efficacy results.

13 BY MR. JONES:

14 Q. And these -- these surgeons discussed
15 those issues at conferences, correct?

16 A. I'm sure they did. I don't
17 specifically remember them.

18 Q. These surgeons discussed those issues
19 with you, though, correct?

20 A. I've had discussions with surgeons
21 about that, yes.

22 Q. And these surgeons also reported these
23 concerns in the medical literature as well,
24 correct?

1 A. Not the ones I spoke to.

2 Q. Okay. What surgeons did you speak
3 with?

4 A. Usually just local --

5 Q. Local surgeons?

6 A. -- local surgeons.

7 Q. Okay. And local surgeons were
8 communicating to you that they had concerns about
9 their results with TVT-Secur correct?

10 A. Yes.

11 Q. Who is Dr. McCauley?

12 A. Lowell McCauley is a gynecologist.

13 Q. Local?

14 A. Yes.

15 Q. Doesn't practice with your group?

16 A. No.

17 Q. Was he one of the surgeons that
18 expressed concerns with his results with TVT-Secur?

19 A. I don't remember if he expressed
20 results -- concerns or not. I honestly don't
21 remember. I didn't keep track of his results. We
22 don't really talk that often.

23 Q. You would have done -- in your role as
24 a consultant for Ethicon, you would have done

1 consulting events in 2008, correct?

2 A. I would have proctored patients or
3 doctors in 2008.

4 Q. In 2008 you did proctor events for
5 Ethicon, correct?

6 A. Yes.

7 Q. Okay. Do you recall how many?

8 A. No.

9 Q. We've already established in 2007 you
10 did proctor events for Ethicon, correct?

11 A. Yes.

12 Q. Okay. Every year from 2005 to 2012 you
13 did proctor events for Ethicon, correct?

14 MR. MORIARTY: Objection.

15 THE WITNESS: I don't remember if I did
16 them in 2012 or not. I wasn't doing -- you know,
17 in the last couple -- the last years before they
18 stopped doing TVT-Secur, I didn't do as many
19 proctoring events, and I can't remember how many I
20 did. So I can't remember how many I did in '12 or
21 '11. I may have done one or two. Again, I don't
22 remember. You may have that information. I don't
23 know.

24 MR. JONES: Okay. Exhibit 28.

1 (Whereupon Exhibit 28 was marked as an
2 exhibit.)

3 BY MR. JONES:

4 Q. Exhibit 28 is a 2008 Ethicon email
5 between Scott Finley and Mike Lewis, correct.

6 A. Yes.

7 Q. Subject line is "Ramsey dinner,"
8 correct?

9 A. Okay.

10 Q. Correct?

11 A. Yes.

12 Q. And then the email is then forwarded on
13 to -- to Bob Zipfel, correct?

14 A. Yes.

15 Q. Scott Finley writes, "Bob, attached is
16 the dinner request that I discussed with you.
17 We've been working on this for a while and feel
18 this is a great step in reaching out to the urology
19 market in Atlanta. Will keep the cost to a
20 minimum. If they don't get the commitment for
21 attendees, we will move to postpone."

22 Did I read that correctly?

23 A. Yes.

24 Q. And Mike Lewis writes, "I wasn't sure

1 whether to list this as an awareness dinner or a
2 training dinner."

3 A. Okay.

4 Q. Correct?

5 A. Correct.

6 Q. And this is in 2008, correct?

7 A. Yes.

8 Q. And it appears that in 2008 Ethicon was
9 considering using you in Atlanta at a dinner
10 presentation, correct?

11 A. They -- they considered it. I don't
12 remember if I did it.

13 Q. Okay. But you know that in 2008
14 Ethicon considered using you for a dinner event in
15 the urology market in Atlanta, correct?

16 A. Right. Correct.

17 Q. And as you sit here today, you're not
18 able to tell us that you did not participate in
19 this 2008 dinner event in Atlanta, correct?

20 A. I can't remember if it went on or not.
21 I don't remember the event.

22 Q. And this would have been a dinner
23 event, though, correct?

24 A. Yes.

1 Q. And if there are invoices in Ethicon's
2 internal files related to this dinner event
3 evidencing that you attended, you won't disagree
4 with those, correct?

5 A. I would not if there were invoices for
6 that.

7 Q. And this would be a dinner event above
8 and beyond the 20 or so proctor events that we
9 talked about yesterday?

10 A. Yes. It doesn't look like this was a
11 proctoring event. It would have been a discussion.

12 Q. Okay. So when you talked about
13 "proctor events," you're not including any
14 potential dinner events that you did for Ethicon,
15 correct?

16 A. I don't think so. I don't know how
17 many I did. Honestly, I don't know the number of
18 any of that off the top of my head.

19 Q. Okay.

20 A. So I don't know.

21 Q. Did you discuss with Ethicon
22 potentially conducting dinner events for Ethicon in
23 2008?

24 A. Maybe. I don't specifically recall it.

1 Q. How were you -- when you did proctor
2 events, how were you paid?

3 A. They would send me a check to my house.

4 Q. They would send you a check to your
5 house made out to Chris Ramsey, correct?

6 A. Correct.

7 Q. Then were you paid based on the number
8 of surgeons that attended?

9 A. I don't know the answer to that,
10 honestly. I don't know how I was paid for that. I
11 think that I would be paid for each -- if I was
12 proctoring a case, if I was watching a surgeon
13 proctor and helping him with that, I would be paid
14 for each individual case.

15 And I don't know if it was a fixed cost
16 for the first one and then a lower cost for the
17 next ones; I'm not sure.

18 With the observations, I probably got
19 paid for each physician that came in --

20 Q. Okay.

21 A. -- but I'm not sure. It was a smaller
22 fee for that.

23 Q. It makes sense you'd get paid -- the
24 more physicians that attended, the more you would

1 get paid, correct?

2 A. It's possible. I'm sure it's in my
3 contract how that was laid out, and I'm not sure.

4 Q. That's a good point. Let's go back to
5 your contracts. Exhibit 5.

6 MR. MORIARTY: Now we're going
7 backwards.

8 BY MR. JONES:

9 Q. Okay. Exhibit 5 we marked yesterday as
10 the 2006 contract between you and Ethicon, correct?

11 A. Yes.

12 Q. Okay. And what is the total contract
13 amount listed?

14 MR. MORIARTY: Objection. Form.

15 THE WITNESS: I don't know. Where does
16 it say that?

17 BY MR. JONES:

18 Q. (Indicating.)

19 A. So \$250 for one hour day -- occasion --
20 \$50 -- oh, is that -- "shall not exceed 50,000 per
21 year." Okay.

22 Q. Okay. Read that into the record, will
23 you, that sentence?

24 A. It says, "The parties agree that

1 compensation paid to the consultant shall not
2 exceed 50,000 per year except as being mutually
3 agreed by the parties."

4 Q. So the 2006 contract you entered with
5 Ethicon, the maximum amount of payments allowed was
6 \$50,000, correct?

7 A. Correct.

8 Q. Let's look go ahead and look at Exhibit
9 6.

10 MR. MORIARTY: Is that the other
11 contract?

12 MR. JONES: Yeah. I'll give it to him.

13 MR. MORIARTY: I just need to know what
14 it was.

15 You marked more contracts than you gave
16 me.

17 MR. JONES: Hmm?

18 MR. MORIARTY: You marked more
19 contracts in the exhibit stack than you gave me. I
20 don't need them.

21 MR. JONES: Okay.

22 MR. MORIARTY: I just need to keep it
23 straight.

24

1 BY MR. JONES:

2 Q. Okay. Take a look at Exhibit 6. I'll
3 direct you to one of the last pages of Exhibit 6
4 that I'm folding over for your convenience.

5 Exhibit 6 is a consulting agreement
6 between you and Ethicon, correct?

7 A. Correct.

8 Q. For the year 2008, correct?

9 A. Where do you see the date?

10 Yep. Yes.

11 Q. Turn to the -- read into the record the
12 sentence starting with "The parties agree."

13 A. -- "that compensation paid to the
14 consultant shall not exceed \$50,000 per year"?

15 Q. Correct.

16 Does this indicate that in 2008 the
17 maximum amount of payments allowed under your
18 consultant contract was \$50,000?

19 A. Yes.

20 Q. Let's look at Exhibit 7.

21 When -- when you were a consultant for
22 Ethicon, were you allowed to use any of your own
23 materials in those proctorships?

24 A. I didn't use any of my own materials.

1 I don't have any materials of my own.

2 Q. And Ethicon had to approve any
3 statements that you made during those proctorships,
4 correct?

5 A. Yes. Specifically to the surgery. I'm
6 sure I said other things to the doctors.

7 Q. Okay. I want you to look at Exhibit 7,
8 which we marked yesterday as a contract between you
9 and Ethicon dated 2009, correct?

10 A. Okay. Yes.

11 Q. And I want you to turn to page 718,
12 Heading Number 12. I want you to read the
13 underlined sentence into the record.

14 MR. MORIARTY: Let me see it first,
15 please.

16 THE WITNESS: "You shall not make any
17 representation relating to company's products or to
18 company's clinical outcomes unless such
19 representations have been reviewed and approved in
20 advance by company."

21 BY MR. JONES:

22 Q. Is that a term you agreed to in that
23 contract?

24 A. Yes.

1 Q. And did you follow that?

2 A. Yes.

3 Q. And is that something that you followed
4 throughout the term of your consulting --

5 A. Yes.

6 Q. -- relationship with Ethicon?

7 A. Yes.

8 Q. Did you know that internally Ethicon
9 considered TVT-Secur a failed product?

10 MR. MORIARTY: Objection. Form.

11 Go ahead.

12 THE WITNESS: I didn't know that.

13 BY MR. JONES:

14 Q. You've never seen any document where
15 Ethicon employees referred to TVT-Secur as a failed
16 product?

17 A. No.

18 Q. You've never seen any internal
19 documents where the engineers who worked on the
20 design of TVT-Secur referred to it as a failed
21 product?

22 A. No.

23 Q. Have you seen any presentations by
24 Ethicon related to TVT-Secur discussing the lessons

1 learned from their failures with TVT-Secur?

2 A. Not in -- no, I have not.

3 Q. Are you familiar at all with the
4 TVT-Secur world registry being shut down?

5 A. No. No.

6 Q. So you're not familiar with the
7 TVT-Secur world registry at all?

8 A. I'm familiar with the term, but I
9 didn't know it was shut down.

10 Q. Okay. And do you know how long it was
11 in existence?

12 A. No.

13 Q. Do you know -- you don't know why --
14 you don't know that it was shut down, so you don't
15 know why it was shut down, correct?

16 A. Correct.

17 Q. Do you know what the adverse event rate
18 was in the TVT-Secur world registry?

19 A. I couldn't quote it. I'd have to look
20 at it.

21 Q. If it was higher than 15 percent, that
22 would be something that would stand out to you,
23 correct?

24 MR. MORIARTY: Objection. Are you

1 talking about efficacy rate? Or something else?

2 BY MR. JONES:

3 Q. Let's go with the -- if the erosion
4 rate in the TVT-Secur world registry was above 15
5 percent, would that stand out to you?

6 A. Well, then, I guess we have to discuss
7 what "erosion" is as opposed to "exposure."

8 Q. We're including the three e's.

9 A. And what are those?

10 Q. You don't know what the three e's are?

11 A. I have no -- I would assume -- we've
12 talked about "exposure" and "erosion." What's the
13 third one?

14 Q. You don't know what the third one is?

15 A. No.

16 Q. Okay. As someone holding yourself out
17 as an expert in transvaginal mesh litigation, you
18 don't know what the third "e" is?

19 A. I've never heard of the term "the three
20 e's" before.

21 Q. Okay. You've never heard of the term
22 "three e's"?

23 A. No.

24 Q. Okay.

1 MR. MORIARTY: Neither have I,
2 actually.

3 (Reporter interruption for
4 clarification.)

5 MR. MORIARTY: I said neither have I,
6 actually, if that matters.

7 BY MR. JONES:

8 Q. May be why he hasn't heard of it.

9 Have you heard of the term "extrusion"?

10 A. I've heard the term "extrusion."

11 Q. Okay. What does that term mean?

12 A. To me, extrusion means that the mesh
13 has come out.

14 Q. Of what?

15 A. Out of the vagina.

16 Q. Is it similar to an erosion?

17 A. No. I would say an -- an erosion is
18 where the mesh actually erodes into a different
19 area of the body outside of the vagina.

20 Q. Okay. Now that we know what the three
21 e's are, would it -- would -- if the exposure,
22 extrusion, or erosion rate was above 15 percent in
23 the TVT-Secur world registry, would that stand out
24 to you?

1 A. I don't think it would be that high.

2 Q. I didn't ask that question.

3 I asked, if it was, would that stand
4 out to you?

5 A. It would be interesting to see.

6 Q. Okay. Do you know one way or other
7 what the erosion rate is in the TVT-Secur world
8 registry?

9 A. I couldn't tell you.

10 Q. Do you know what the failure rate is?

11 A. There are multiple failure rates. But
12 in the registry, I don't know.

13 MR. MORIARTY: When it's convenient,
14 let's take a quick break.

15 MR. JONES: Let's take a quick break.
16 Let's take a quick break.

17 (Brief recess.)

18 BY MR. JONES:

19 Q. Doctor, after a short break, we're back
20 on the record. Are you ready to proceed?

21 A. Yes.

22 (Whereupon Exhibit 29 was marked as an
23 exhibit.)

24

1 BY MR. JONES:

2 Q. I've marked Exhibit 9 [verbatim], which
3 is a printout from Tennessee Urology Associates'
4 website.

5 Do you recognize this?

6 A. Yes.

7 Q. Is this your website?

8 A. It looks like it. It's brand new.

9 Q. Okay. And under -- at the bottom of
10 page 1, under "Da Vinci Surgery Providers," there's
11 a paragraph explaining background information about
12 yourself, correct?

13 A. Right.

14 Q. It reads, "Dr. Ramsey's practice has a
15 special concentration in robot-assisted
16 laparoscopic procedures," correct?

17 A. Yes.

18 Q. And does it state anywhere on this
19 website that you have a special concentration in
20 treatment of female SUI?

21 A. Well, this is the da Vinci surgery page
22 on our -- on our website. And under a bio of
23 myself, there should be -- and if there's not, I
24 need to correct it because this is -- it's a

1 relatively -- we have a new website that we have
2 through our company.

3 Our old website had all the procedures
4 we used to use, and this is new. So I haven't
5 looked at it since this has been done. But it
6 should say all the things that I provide, including
7 stone surgery, treatment of the cancers --

8 Q. Okay.

9 A. -- erectile dysfunction, stress
10 incontinence.

11 So -- but this is a specific link on
12 that. This isn't just my page; this is a -- the
13 da Vinci page for patients who are interested in
14 that part.

15 Q. Okay. Your website profile is listed
16 in the da Vinci surgery website on Tennessee
17 Urology Associates, correct?

18 A. Say that one more time.

19 Q. Your profile is listed on the da Vinci
20 surgery website on Tennessee Urology Associates,
21 correct?

22 A. I guess I don't know what you mean by
23 "the da Vinci surgery website."

24 Q. The da Vinci section.

1 A. The section, yes.

2 MS. MEAD: Madam Court Reporter?

3 (Off-the-record discussion.)

4 BY MR. JONES:

5 Q. So at least according to this exhibit,
6 nowhere do you list any special concentration or
7 emphasis --

8 (Off-the-record discussion.)

9 BY MR. JONES:

10 Q. All right. Doctor, let's proceed.

11 According to Exhibit 29, which is a
12 section of the Tennessee Urology Associates
13 website, you don't list any special concentration
14 in treating female SUI, correct?

15 A. It wouldn't be on that page.

16 Q. Okay. If -- if it is on the website, I
17 can go there and pull it; we'll find it, right?

18 A. If it is on there, yeah.

19 Q. Okay.

20 A. And if it it's not, I want to know so I
21 can get it updated --

22 Q. That's fine.

23 A. -- so thanks for checking.

24 (Whereupon Exhibit 30 was marked as an

1 exhibit.)

2 BY MR. JONES:

3 Q. Let's look at Exhibit 30. Tell me what
4 Exhibit 30 is.

5 A. It's a Tennova Hospital. It's one of
6 the local hospital chains.

7 MR. MORIARTY: Do I get one?

8 MR. JONES: Yeah.

9 BY MR. JONES:

10 Q. Do you practice there?

11 A. That's where I do some of my surgeries.

12 Q. Okay. Anywhere on this website does it
13 state you have a special concentration in treating
14 female SUI?

15 A. It does not.

16 Q. Okay. It does state you have a special
17 concentration in robotic-assisted -- robotic-
18 assisted laparoscopic surgery, though, correct?

19 A. Yes.

20 Q. You can put that aside.

21 (Whereupon Exhibit 31 was marked as an
22 exhibit.)

23 BY MR. JONES:

24 Q. Do you believe that in -- serving as a

1 consultant for Ethicon for a period of six or seven
2 years presented any potential perceived conflict of
3 interest when you agreed to be a litigation expert
4 witness for Ethicon?

5 A. I don't think so.

6 Q. None whatsoever?

7 A. No.

8 Q. Would you agree that under the current
9 standards, you need to disclose as a potential
10 conflict of interest for yourself your role as a
11 consultant with Ethicon?

12 MR. MORIARTY: Objection. To disclose
13 in what setting?

14 THE WITNESS: To whom?

15 BY MR. JONES:

16 Q. Disclose to patients.

17 MR. MORIARTY: Objection.

18 Go ahead and answer.

19 THE WITNESS: No, I don't.

20 BY MR. JONES:

21 Q. Disclose to other surgeons?

22 A. I don't have an ethical need to
23 disclose it to other surgeons, no.

24 Q. You don't have an ethical need to

1 disclose it to patients, that you're a consultant
2 for Ethicon?

3 A. I don't have to, no.

4 Q. Okay. When you're counseling patients
5 on whether an Ethicon mesh product is appropriate
6 for them, you don't feel any ethical need to tell
7 them that you were an Ethicon consultant, correct?

8 A. I have told them that. I don't use it
9 as a routine part of my discussion with surgery,
10 though. In certain patients, I do.

11 Q. So you didn't feel the ethical need to
12 tell them that, correct?

13 A. Not every patient, no.

14 Q. If you were going to write a journal
15 article today, you would have to disclose as a
16 potential conflict of interest your work as a
17 consultant for Ethicon and your work as a
18 consultant for AMS, correct?

19 A. If I was going to do it today, I don't
20 think that I would have to disclose my work as a
21 consultant for Ethicon right now, since I'm not
22 proctoring any of their surgeries right now. But
23 for AMS, I would.

24 Q. Okay. If you wrote today a journal

1 article on transvaginal mesh for the treatment of
2 SUI, you would disclose as a potential conflict of
3 interest your consultant relationship with AMS,
4 correct?

5 A. Correct.

6 Q. If you wrote a journal article today on
7 treating SUI with transvaginal mesh, you would not
8 disclose your relationship with Ethicon currently?

9 MR. MORIARTY: Objection.

10 THE WITNESS: I don't have a current
11 relationship with Ethicon.

12 BY MR. JONES:

13 Q. You wouldn't disclose that you're a
14 litigation expert witness for Ethicon in a journal
15 article you were writing on treating SUI with
16 transvaginal mesh?

17 A. I don't think that I would have to -- I
18 would consult an attorney -- or I would consult
19 the people who knew that type of thing. I do not
20 think that I would need to because I've never seen
21 anybody else do that in their -- in their
22 disclosures, that they are involved in litigation.

23 Q. You've never seen a conflict of
24 interest disclosure in a medical journal article

1 where an author has disclosed that they're a
2 litigation expert witness?

3 A. Not that I recall.

4 Q. If you wrote a journal article today in
5 the context of treating female SUI with
6 transvaginal mesh, would you need to disclose your
7 past consulting relationship with Ethicon?

8 A. I don't -- I don't know if I would need
9 to do that. I don't think I need to do that. I
10 think it's just current at the time of the article.

11 If it related maybe to procedures that
12 I had done with them, I would probably do that.

13 Q. Okay. So if you wrote a journal
14 article today on the TVT-Secur device, you would
15 disclose in your conflict of interest statement
16 that you previously served as a consultant for
17 Ethicon, correct?

18 A. Yes.

19 Q. Why?

20 A. I think that's the ethical thing to do,
21 let the -- as we discussed the same thing
22 yesterday, that it allows the reader to see who
23 wrote the article and what potential biases they
24 have in writing the article so they can come to

1 their own conclusion about the validity of the
2 results I would come up with.

3 Q. So in a journal article you would write
4 on the TVT-Secur device, you would feel the need to
5 disclose as a potential conflict of interest your
6 past consulting work for Ethicon, correct?

7 A. Not necessarily.

8 Q. Would you disclose it?

9 A. If it was in relation to TVT-Secur
10 devices that I've used -- if it was specifically
11 with TVT, not specific with transvaginal mesh.

12 Q. Okay. So you're writing a journal --

13 A. Yes, sir.

14 Q. -- article today on TVT-Secur device.
15 Got me?

16 A. Yes.

17 Q. Would you feel an ethical need to
18 disclose as a potential conflict of interest in
19 your TVT-Secur article that you had been a
20 consultant for Ethicon --

21 A. Previously --

22 Q. -- in prior years?

23 A. I would. Previously.

24 Q. And that's because your consulting work

1 for Ethicon in prior years related to TVT-Secur,
2 correct?

3 A. Correct.

4 Q. And because your prior consulting work
5 for Ethicon involved TVT-Secur, you would feel an
6 ethical need to disclose as a potential conflict of
7 interest your role as a consulting physician on
8 TVT-Secur, correct?

9 A. That's a pretty long sentence. Can you
10 read that back again? I lost you after the
11 first --

12 Q. I think I. . .

13 Let me strike that.

14 Your potential -- your consulting work
15 for Ethicon in relationship to TVT-Secur presents a
16 potential conflict of interest for a reader of a
17 TVT-Secur article that you would write today?

18 MR. MORIARTY: Objection. Form.

19 Go ahead.

20 THE WITNESS: A reader could
21 potentially see that as a bias.

22 BY MR. JONES:

23 Q. When did you first learn that Ethicon
24 was going to stop selling the TVT-Secur device?

1 A. I think the letter came out in May of
2 '12.

3 Q. May 2012 is when you first learned
4 Ethicon would stop selling the TVT-Secur device,
5 correct?

6 A. Yes.

7 Q. You know that in January 2012 Ethicon
8 received the 522 order on TVT-Secur, correct?

9 A. I can't remember the exact date.

10 Q. But you know in 2012 Ethicon's
11 TVT-Secur device was subject to a 522 order?

12 A. Yes.

13 Q. And I take it you continued to use
14 TVT-Secur after May 2012, correct?

15 A. Correct.

16 Q. And you continued to use the TVT-Secur
17 device after you were made aware that there was a
18 522 order on the TVT-Secur device, correct?

19 A. Yes.

20 Q. And on those patients that you
21 implanted the TVT-Secur device with, after you
22 learned the TVT-Secur device was subject to a 522
23 order, did you tell them?

24 A. No. Unless they asked a question.

1 Q. You didn't tell your patients the
2 TVT-Secur device was subject to a 522 order when
3 you implanted it in them?

4 A. No.

5 Q. Did you tell those patients that
6 Ethicon had decided to stop selling the device?

7 A. Towards the end, when I knew I was
8 going to run out, I would explain to the patient
9 that if -- if this TVT-Secur was not available,
10 then I would use a different device. That's what
11 I'm doing with MiniArc-Precise.

12 So I would explain, if this is
13 available, this is what I'm going to use, because I
14 like it. I get good results with it. If it's not
15 available, here's the one we're going to use.

16 So I would consent them for both there
17 towards the end. But when I knew it was still in
18 supply, I did not tell them that it was not going
19 to be available after August or whenever it was
20 going to stop being made.

21 Q. Some patients that you implanted the
22 TVT-S in, you didn't tell them that Ethicon had
23 already told you that they would stop selling the
24 TVT-S device, correct?

1 A. Correct. After May.

2 Q. We talked a little bit about the 2011
3 FDA panel or advisory -- advisory committee
4 earlier.

5 A. Okay.

6 Q. You're just not aware of the nature of
7 the 2011 FDA panel, correct?

8 A. The panel that came up with it, I don't
9 know who was on it or how they came up with the
10 statement -- they had -- their warning that came
11 out, that's what I'm aware of. I read that letter.

12 Q. Okay. And are you aware of the 2011
13 FDA advisory committee?

14 A. I'm aware of the name. I don't know
15 who was on it or how that was --

16 Q. Have you read -- are you familiar with
17 the meeting that took place?

18 A. I'm not aware of the meeting.

19 Q. Are you aware of the meeting minutes?

20 A. No.

21 Q. Have you reviewed a summary of that
22 meeting?

23 A. Not that I'm aware of.

24 Q. Have you reviewed any reports or

1 testimony from Ethicon that occurred at that
2 meeting?

3 A. No.

4 Q. Has Ethicon showed you any internal
5 documents that they have related to that meeting?

6 A. I don't remember seeing those.

7 Q. Has Ethicon showed you the FDA file for
8 that meeting?

9 A. No.

10 Q. Okay. Do you understand what the
11 Freedom of Information Act is, request is?

12 A. I'm aware of it.

13 Q. Okay.

14 A. Never done one.

15 Q. Okay. Ethicon has never shown you the
16 Freedom of Information Act request that they filed
17 for the 2011 FDA advisory committee meeting?

18 A. No.

19 Q. Okay. You've never seen it, correct?

20 A. No.

21 Q. Are you familiar with what conclusions
22 the FDA advisory committee made with regards to
23 mini-slings?

24 A. I can't remember the exact wording

1 about mini-slings.

2 Q. What was the general wording?

3 A. There was concern about efficacy of the
4 mini-slings.

5 Q. In 2011, a panel of experts was
6 convened, and that panel expressed concerns about
7 the efficacy of mini-slings, correct?

8 A. Again, I'm not sure what the panel
9 said. I just know what the statements --

10 Q. You're not sure what the panel said in
11 2011, correct?

12 A. Correct.

13 Q. And because you're not sure what the
14 panel said in 2011, that's not information you
15 would have told your patients, correct?

16 A. Correct.

17 Q. And I take it in 2011 you weren't
18 following these meetings of the advisory committee,
19 correct?

20 A. I wasn't following them.

21 Q. Okay. You weren't keeping up to date
22 with the advisory committee meetings in 2011,
23 correct?

24 A. Not the advisory meetings.

1 MR. JONES: All right. Got to do this.

2 Exhibit 31.

3 (Whereupon Exhibit 31 was marked as an
4 exhibit.)

5 BY MR. JONES:

6 Q. Take a look at the email. Just going
7 to ask you whether that was in your email and what
8 you sent, and whether that clears up an issue you
9 raised earlier today.

10 A. (Reviews document.)

11 Q. All right. This is a 2009 email sent
12 by you, correct?

13 A. Yes.

14 Q. And does this refresh your memory now
15 that this was an email address used by you?

16 A. It does, but I still don't remember it
17 being charter.net.

18 Q. Got it.

19 A. I haven't used it in a long time.

20 Q. Got it. But you're not disputing that
21 you sent an email from this account, correct?

22 A. No.

23 Q. And this is a 2009 email from you with
24 a subject line titled "TVT-O dinners," correct?

1 A. Yes.

2 Q. Who is -- who is Julie Ramsey?

3 A. That's my wife. I took -- I put
4 anything I do past her before I do it.

5 Q. She's got the chartertn.net email
6 address, but you don't, correct?

7 A. She has a chartertn.net and I have --
8 she has a charter.net, I have a chartertn.net, is
9 what I remember.

10 Q. Okay. But --

11 A. But we've switched to Gmail.

12 Q. But not according to this email,
13 correct?

14 A. Yeah.

15 Q. All right. This indicates that you
16 were going to do a TVT-O dinner in Greeneville,
17 Tennessee, correct?

18 A. It looks like it.

19 Q. In 2009, correct?

20 A. Yes.

21 Q. In 2009 you did a TVT-O dinner event in
22 in Greeneville, correct?

23 A. I don't know if I did it. But that was
24 one that -- that they were asking me about. I

1 don't remember doing -- honestly, I don't remember
2 doing it.

3 Q. You write -- you write back, "I can do
4 any date except August 26th. Mike Lewis has me
5 going to Greeneville on September 16th," correct?

6 A. Yes.

7 Q. So you went to Greeneville for Ethicon
8 on September 16th, correct?

9 A. I don't remember going to Greeneville.

10 Q. According to this exhibit, your Ethicon
11 sales rep sent you to Greeneville on September
12 16th, correct?

13 A. That was -- looks like the plan, but I
14 don't remember it.

15 Q. Okay. And the plan was for a TVT-O
16 dinner on August 26th, correct?

17 A. That looks like that's what the plan
18 was.

19 Q. Okay. So the plan was for you to do a
20 TVT-O dinner event August 26th, 2009, correct?

21 A. Looks like it, yes.

22 Q. And then, a few weeks later, the plan
23 was for you to do a event in Greeneville on
24 September 16th, 2009, correct?

1 A. That was the plan.

2 Q. So that would have been two Ethicon
3 events in less than three weeks, correct?

4 A. If they occurred.

5 Q. Okay. You were planning on doing two
6 Ethicon events in 2009 in less than three weeks,
7 correct?

8 A. Looks like we were trying to coordinate
9 that or organize that.

10 Q. Okay. You were trying to do two
11 different Ethicon events in three weeks in 2009,
12 correct?

13 A. I was, again, trying to coordinate
14 that, yes.

15 MR. JONES: Okay. You can put that one
16 away.

17 (Whereupon Exhibit 32 was marked as an
18 exhibit.)

19 MR. MORIARTY: Exhibit 32.

20 MR. JONES: Exhibit 32.

21 THE WITNESS: This says 33.

22 BY MR. JONES:

23 Q. I'll mark for the record Exhibit 32,
24 which is an email -- Ethicon email dated July 2009,

1 correct?

2 A. Yes.

3 Q. Scott Finley wrote this email, correct,
4 the top email?

5 A. Yes.

6 Q. He writes, "I'm looking at utilizing
7 Chris Ramsey to go after urologists in Atlanta,
8 Greeneville, and Charleston for TVT-O."

9 Did I read that correctly?

10 A. Yes.

11 Q. Did you ever consider yourself as
12 "going after" urologists in Atlanta, Greeneville,
13 and Charleston for TVT-O?

14 A. I would never have put it that way.

15 Q. You would never have used the term
16 "going after" urologists in other markets for
17 Ethicon products, correct?

18 A. Correct.

19 Q. Scott Finley stated you were going
20 after urologists in different markets for TVT-O,
21 correct?

22 A. Repeat that again.

23 Q. Scott Finley stated you were -- they
24 wanted to utilize you to go after urologists in

1 other markets for TVT-O, correct?

2 A. That was his wording, yes.

3 Q. Okay. And Scott Finley was your
4 Ethicon sales rep at one time or another, correct?

5 A. Correct.

6 Q. And he was also your division sales rep
7 manager, correct?

8 A. Correct.

9 Q. And he stated he wanted to use you to
10 go after other -- other urologists in Atlanta,
11 Greeneville, and Charleston for TVT-O, correct?

12 A. That's what he said.

13 Q. Okay. In 2011, why did you stop using
14 TVT-Secur?

15 A. I didn't.

16 Q. Did your use of TVT-Secur decrease in
17 2011?

18 A. I don't think so.

19 Q. At all?

20 A. Not that I know. Not -- not
21 consciously, it didn't.

22 MR. JONES: I'll mark Exhibit 33.

23 (Whereupon Exhibit 33 was marked as an
24 exhibit.)

1 BY MR. JONES:

2 Q. It's dated January 25th, 2011, correct?

3 A. Okay. Yes.

4 Q. And this is an email from Jason Martin
5 to Scott Finley, correct?

6 A. Yes.

7 Q. Jason Martin was Ethicon's sales rep
8 for you, correct?

9 A. Yes.

10 Q. And Scott Finley was your Ethicon sales
11 rep division manager, correct?

12 A. Correct.

13 Q. And the subject line is "Field ride
14 agenda and opportunity win/losses," correct?

15 A. Yes.

16 Q. Okay. And Mr. Martin emails his
17 manager, Scott, and says, "Here's my agenda for
18 opportunity wins and losses. We can discuss more
19 next week," correct?

20 A. Yes.

21 Q. "We have a 7:45 appointment with
22 Dr. Ramsey tomorrow," correct?

23 A. Yes.

24 Q. Seems like Mr. Martin and Mr. Finley

1 were going to come visit you in 2011 at your
2 hospital, correct?

3 A. Yes.

4 Q. The second page is the attached field
5 ride agenda.

6 A. Right.

7 Q. "Day 1, Ramsey appointment, 7:45 at
8 office. Discuss Abbrevio and Secur," question mark,
9 question mark. Parenthetical, "Why no cases on
10 Secur?"

11 Did I read that correctly?

12 A. Yes.

13 Q. Why no cases on TVT-Secur, Dr. Ramsey,
14 in 2011, in January?

15 A. I have no idea what he means by that
16 line. I don't know what it's in reference to.

17 Q. Day 2 -- Day 2, fourth bullet point --
18 go ahead. I cut you off.

19 A. No, no. Go ahead.

20 Q. Day 2, fourth bullet point says
21 "Promote dinner program."

22 Do you know what that means?

23 A. I'm sure there's some type of dinner
24 program that he wants to get surgeons to go to.

1 Q. Okay. You can put that one away.

2 So what do you think he was referring
3 to when I cut you off earlier about why no
4 TVT-Secur cases?

5 A. I can't speak to that at all. I have
6 no idea. I don't remember stopping them -- or not
7 doing -- I remember continuing doing them. That
8 was the procedure that I used of choice and
9 continued to do it.

10 Q. The TVT-Secur is your sling of choice,
11 correct?

12 A. It was my sling of choice.

13 Q. Today, what's your sling of choice?

14 A. Today still the MiniArc-Precise.

15 Q. Today your sling of choice is the AMS
16 MiniArc-Precise, correct?

17 A. Yes.

18 Q. For the last eight years, your sling of
19 choice has been the mini-sling, correct?

20 A. The mini-sling, yes.

21 (Whereupon Exhibit 34 was marked as an
22 exhibit.)

23 BY MR. JONES:

24 Q. Exhibit 34. I just want to direct your

1 attention to the bottom of page 1.

2 A. Okay.

3 Q. Okay. And now we're going to start at
4 the very last page.

5 This is an email in 2009 to you,
6 correct?

7 A. Yes.

8 Q. Scott Finley's copied on the email,
9 correct?

10 A. Yes.

11 Q. Subject line is "TVT-O dinners,"
12 correct?

13 A. Yes.

14 Q. And Ethicon writes to you, Dr. Ramsey,
15 and says, "Let me know five Thursdays that you're
16 available to travel and deliver TVT-O dinner
17 lectures in Scott Finley's division," correct?

18 A. Correct.

19 Q. "Your flights would need to depart on
20 Thursday afternoon and you could fly home the first
21 thing Friday morning. You will be compensated for
22 one full day per your 2009 Ethicon consulting
23 agreement."

24 Did I read that correctly?

1 A. Yes.

2 Q. And then he follows up 16 minutes later
3 and writes, "Or five Wednesdays, since you are off
4 on Thursdays."

5 Did I read that correctly?

6 A. Where is that? Second page?

7 Q. Last page.

8 A. Last page?

9 Yes.

10 Q. What does he mean, "You're off on
11 Thursdays"?

12 A. Thursday is my day off.

13 Q. Okay. Then you get -- you jump five
14 days forward to July 11th, 2009, and he emails you
15 again.

16 He says, "Hi, Dr. Ramsey, are you
17 interested in delivering TVT-O dinner
18 presentations?"

19 Did I read that correctly?

20 A. Yes.

21 Q. And you write back, "Yes, I am."

22 Did I read that correctly?

23 A. Yes.

24 Q. In 2009 you were interested in giving

1 TVT-O dinner presentations on behalf of Ethicon,
2 correct?

3 A. Yes.

4 Q. You write on 2009, July 14th, to
5 Ethicon, "I'm not ignoring you," exclamation point.
6 "I'm still trying to coordinate with my wife and
7 work. Mike, can you remind me when we are going to
8 Greeneville? Bob, what are the open dates again?
9 Thanks."

10 Did I read that correctly?

11 A. Yes.

12 Q. And do you recall how many dinner --
13 TVT-O dinner events you ended up doing for Ethicon
14 in 2009?

15 A. I don't remember at all.

16 Q. You just know that you were interested
17 in doing them?

18 A. Yes.

19 Q. What is a TVT-O dinner event?

20 A. It's a dinner event where I'll sit down
21 with a couple of docs and we'll just talk about
22 surgery.

23 Q. And it's a marketing event, correct?

24 (Reporter interruption for

1 clarification.)

2 BY MR. JONES:

3 Q. These events are marketing events,
4 correct?

5 A. It would be a marketing event for
6 Ethicon, yes.

7 Q. Okay. And you were interested in
8 participating in marketing events for Ethicon in
9 2009, correct?

10 MR. MORIARTY: Objection. Form.

11 Go ahead.

12 THE WITNESS: I was interested in
13 discussing the surgery.

14 BY MR. JONES:

15 Q. Okay. You were interested in
16 participating in dinner events for Ethicon in 2009,
17 correct?

18 A. Yes.

19 Q. On the TVT-O, correct?

20 A. Yes.

21 Q. And in 2009, TVT-O was not your sling
22 of choice, correct?

23 A. Correct.

24 Q. But you were still interested in doing

1 dinner events on TVT-O in 2009 for Ethicon,
2 correct?

3 A. Yes.

4 MR. JONES: Exhibit 35.

5 (Whereupon Exhibit 35 was marked as an
6 exhibit.)

7 THE WITNESS: Which page is that?

8 BY MR. JONES:

9 Q. Page 2. Exhibit 35 is an Ethicon 2009
10 email with the subject line "Consulting fees for
11 Dr. Lucente," correct?

12 A. Okay.

13 Q. And it reads in part, "Hi, Melissa. I
14 was able to find Dr. Katherine Cameron. She was
15 trained by the following: March 28th, 2008, Chris
16 Ramsey, TVT-Secur preceptorship."

17 Did I read that correctly?

18 A. Yes.

19 Q. All right. Did you train Dr. Katherine
20 Cameron on the TVT-Secur?

21 A. Looks like I did, yes.

22 Q. And Dr. Katherine Cameron is one of
23 your partners, correct?

24 A. Correct.

1 Q. You guys practice in the same clinical
2 practice group?

3 A. Yes.

4 Q. You trained her on TVT-S in 2008,
5 correct?

6 A. Correct.

7 Q. And you trained Dr. Newport on TVT-S,
8 as well, correct?

9 A. I probably did.

10 Q. Any other of your partners you trained
11 on TVT-Secur?

12 A. I probably trained Dr. Parker and
13 Dr. Nicely.

14 Q. And fair to say that, for Dr. Parker,
15 Nicely, Cameron and Newport, you introduced them
16 to -- introduced them to the TVT-Secur device?

17 A. I would say I trained them on how to
18 use it.

19 Q. Did those doctors that you're partners
20 with thereafter adopt TVT-Secur?

21 A. Well, I think Dr. Parker did. I don't
22 think Dr. Newport did. I can't remember if
23 Dr. Nicely did. And I'm not sure about Cameron
24 either.

1 Q. Okay. Dr. Newport, why did Dr. Newport
2 not adopt TVT-Secur after you trained him on
3 TVT-Secur?

4 A. I don't know. I think he felt more
5 comfortable with the TVT-O.

6 Q. And that goes back to some surgeons had
7 concerns about their results with TVT-Secur,
8 correct?

9 MR. MORIARTY: Objection. Form.

10 THE WITNESS: No. I think it has
11 everything to do with just their individual
12 preference.

13 MR. JONES: Okay. Let's go on to the
14 next one.

15 BY MR. JONES:

16 Q. Did you do TVT-Secur events in 2010 for
17 Ethicon?

18 A. Possibly.

19 Q. More likely than not, did you do events
20 for Ethicon in 2010?

21 A. If you show me one I did. I don't
22 remember.

23 Q. I'm trying to save time. Trying to
24 save time.

1 A. Yeah.

2 Q. So more likely than not, in 2010 you
3 did events in 2010 as a consultant, correct?

4 A. Correct.

5 Q. Okay. Same for 2012: More likely than
6 not you did events for Ethicon as a consultant in
7 2012, correct?

8 A. I honestly don't remember 2012.

9 MR. JONES: We'll mark Exhibit 36.

10 (Whereupon Exhibit 36 was marked as an
11 exhibit.)

12 BY MR. JONES:

13 Q. Take a look at Exhibit 36.

14 MR. MORIARTY: You got one for me, sir?

15 MR. JONES: Oh, yeah. Sorry, sir.

16 THE WITNESS: Okay.

17 BY MR. JONES:

18 Q. Did you do TVT-Secur consulting events
19 for Ethicon in 2012?

20 A. Yes. Looks like I trained Dr. Newport
21 in 2012. That's why I don't remember it, because
22 it looks like it was supposed to be 2011 but he had
23 had a baby.

24 Q. Did you ever have -- Ethicon ever take

1 you to Ruth's Chris Steakhouse in Knoxville?

2 A. Possibly.

3 Q. More likely than not, Ethicon took you
4 to Ruth's Chris Steakhouse in Knoxville, correct?

5 A. Yes.

6 Q. On multiple occasions, correct?

7 A. I don't know how many occasions.

8 Q. Okay. As you sit here today, you can't
9 tell us how many times Ethicon took you to Ruth's
10 Chris Steakhouse in Knoxville, correct?

11 A. I haven't been to Ruth's Chris
12 Steakhouse that many times in my life here in
13 Knoxville. So I would say it's not more than one
14 or two.

15 Q. Okay.

16 A. But I don't know.

17 Q. Fair to say that you received in
18 2009 -- when -- you expressed interest in doing
19 TVT-O dinner events in 2009 for Ethicon, correct?

20 A. Yes.

21 Q. Is it fair to say that, more likely
22 than not, you would have received TVT-O dinner
23 presentation materials leading up to those dinner
24 events, correct?

1 A. I'm not sure what materials I would
2 have been given, because I usually don't use a
3 whole lot of materials.

4 (Whereupon Exhibit 37 was marked as an
5 exhibit.)

6 BY MR. JONES:

7 Q. Exhibit 37. Take a look at that.

8 A. Right.

9 Q. 2009 email to you, correct?

10 A. Correct.

11 Q. And it -- the email contains a TVT-O
12 dinner PowerPoint, correct?

13 A. Yes.

14 Q. For your upcoming dinners, correct?

15 That's what it says in the email,
16 correct?

17 A. Where does it say --

18 Q. "TVT dinner PowerPoint is for your
19 upcoming dinners"?

20 A. Yes.

21 MR. MORIARTY: Do you have one for me?

22 MR. JONES: Sorry. Always. Always.

23 BY MR. JONES:

24 Q. TVT family of products, preceptorship

1 PowerPoint, correct?

2 A. Yes.

3 Q. TVT-O dinner PowerPoint, correct?

4 A. Yes.

5 Q. Prolift+M preceptorship PowerPoint,
6 correct?

7 A. Yes.

8 Q. Prolift+M materials science PowerPoint,
9 correct?

10 A. Yes.

11 Q. Prolift+M complications PowerPoint,
12 correct?

13 A. Yes.

14 Q. Prolift+M dinner PowerPoint, correct?

15 A. Yes.

16 Q. These are all sent to you, correct?

17 A. Correct.

18 Q. In 2009?

19 A. Yes.

20 Q. By Bob Zipfel?

21 A. Yes.

22 Q. Bob Zipfel is professional education
23 manager at Ethicon, correct?

24 A. I guess so.

1 Q. According to this email, he is,
2 correct?

3 A. Yes.

4 Q. And according to this email, these were
5 sent to your home address, correct?

6 A. Correct.

7 Q. Okay. Did you go to Sonoma,
8 California, or Napa Valley?

9 A. Sorry. It was sent to my -- my office
10 address.

11 Q. It was sent to your office address?

12 A. Correct.

13 Q. Okay. "It is probably better if you
14 send things to my home address."

15 A. That's where they wanted to send it,
16 was there. I'm not sure where I got it, but. . .

17 Q. No. This is you writing.

18 A. Right. Right. No, I understand.

19 Q. "However, it's probably better if you
20 send things to my office [verbatim] address," and
21 you list your home address there; is that correct?

22 A. Correct.

23 Q. Okay. Did you go to Napa Valley to the
24 Ethicon summit?

1 A. No. I've never been to Napa Valley.

2 Q. Did you get invited to it?

3 A. I may have been.

4 Q. You just decided it wasn't important
5 for you to go?

6 A. I decided I couldn't go.

7 Q. You wanted to go; you just couldn't go,
8 right?

9 A. No, not necessarily. It's a long way
10 away. I don't think that I could arrange time for
11 it.

12 Q. Okay.

13 A. So --

14 Q. It wasn't something that you were able
15 to arrange time for and attend, correct?

16 A. Correct.

17 Q. And did you have any interest in
18 attending the summit in Sonoma, California in 2011
19 Ethicon held?

20 A. I don't know if I have interest in it
21 or not. I'm not a wine drinker.

22 Q. Okay. Did you get invited to the
23 Ethicon summit in Long Beach, California, in 2010?

24 A. I may have been.

1 Q. Did you attend?

2 A. I don't think so. I'm sure I didn't.

3 Q. Okay. Same reason: That's a long way
4 to go?

5 A. Correct.

6 Q. Long way to travel, right?

7 A. Correct.

8 Q. You would have to take time away from
9 your patients, correct? Time away from your
10 family, correct?

11 A. Correct.

12 Q. Did the FDA ever approve the TVT-Secur
13 device?

14 MR. MORIARTY: Objection. Form.

15 Go ahead.

16 THE WITNESS: Yes.

17 BY MR. JONES:

18 Q. Did the FDA approve the TVT-O device?

19 A. Yes.

20 Q. The TVT Retropubic device, did the FDA
21 approve that?

22 A. Yes.

23 Q. Did the FDA approve the Prolift device?

24 A. I assume they did. I never used it,

1 so --

2 Q. Okay. I'll strike that question.

3 Withdraw that question. Won't use that one.

4 Never attended any of the annual

5 Ethicon summits, outside of the one time you

6 visited New Jersey, correct?

7 A. Not that I remember.

8 Q. Okay. Not that you remember, so it's

9 possible?

10 A. I didn't.

11 Q. Okay. You didn't?

12 A. (Witness moves head up and down.)

13 Q. Last couple questions. Are you

14 familiar with the article "TVT-Secur single-

15 incision sling after 5 years of follow-up: The

16 promises made and the promises broken"?

17 A. I may have read that. I'm not

18 certain --

19 Q. Sort of a significant title, "promises

20 made and promises broken."

21 A. Who wrote it?

22 Q. Francois Haab.

23 A. Haab. I'm not familiar with that,

24 but --

1 Q. Okay.

2 A. -- I'm not -- I'm not very familiar
3 with the article. I may have read it.

4 Q. If it's not on your reliance list,
5 you're not relying on it, correct?

6 A. If it's not on my reliance list, I
7 probably did not read it.

8 Q. Okay. But a title like that, promises
9 made and promises broken with TVT-Secur, would be
10 kind of -- sticks out, correct?

11 A. Sure. What journal was that in? Does
12 it say?

13 Q. "Urology."

14 A. Okay.

15 Q. 2012.

16 A. Okay.

17 Q. Not familiar with it?

18 A. Not off the top of my head.

19 Q. Not on your reliance list?

20 A. I don't know.

21 Q. Feel free, if you want to take -- go
22 off the record and look at your reliance list and
23 see if it's on there.

24 THE WITNESS: Do you have my reliance

1 list?

2 MR. MORIARTY: Have you already looked?

3 MR. JONES: It's not on there.

4 THE WITNESS: Okay. It would take me a
5 while to look through it.

6 BY MR. JONES:

7 Q. So if you'll -- you can look at another
8 time, but based on the representation that it's not
9 in your reliance list, it's an article that you
10 won't be relying on, correct?

11 A. Correct.

12 Q. Okay. And you're not familiar with it,
13 correct?

14 A. No, I don't remember the article.

15 Q. Okay. Have you read any TVT-Secur
16 articles by Dr. Newman?

17 A. Newman? Not that I know of.

18 Q. Okay. Have you seen any -- has Ethicon
19 shown you any internal memos or communications from
20 Dr. Newman about the TVT-Secur device?

21 A. I wouldn't know.

22 Q. None that stand out as you sit here
23 today?

24 A. I don't recollect Dr. Newman.

1 Q. Okay.

2 A. I may recollect the content of it, but
3 I don't recollect the name.

4 Q. Okay. Well, it would stand out if
5 Ethicon showed you communications from Dr. Newman
6 stating that TVT-Secur was --

7 (Reporter interruption for
8 clarification.)

9 BY MR. JONES:

10 Q. -- that TVT-Secur was unsafe, correct?

11 A. I don't remember any article -- any
12 documentation from Dr. Newman.

13 Q. Okay. You don't remember any article
14 from Dr. Newman on TVT-Secur --

15 A. No.

16 Q. -- correct?

17 You don't remember any memos or
18 communications from Dr. Newman to Ethicon regarding
19 TVT-Secur, correct?

20 A. Not specifically Dr. Newman, no.

21 MR. JONES: We'll mark this as the next
22 exhibit, 38.

23 (Whereupon Exhibit 38 was marked as an
24 exhibit.)

1 BY MR. JONES:

2 Q. Briefly look at it. Just tell me if
3 you've seen it before. That's the only question I
4 have.

5 A. (Reviews document.)

6 MR. JONES: Here you go, Counselor.

7 THE WITNESS: I don't remember anything
8 called "brand equity study."

9 BY MR. JONES:

10 Q. Okay. And if that ETH.MESH number is
11 not on your reliance list, it's not a document that
12 you're going to be relying on, correct?

13 A. I don't think I would rely on it.

14 Q. Okay. Are you aware -- did Ethicon
15 show you any documents related to TVT-Secur
16 performance in Australia?

17 A. I've seen that.

18 Q. You've seen that?

19 A. Yes.

20 Q. What happened?

21 A. They were having -- they were having
22 results that weren't as good as they wanted.

23 Q. Okay. Prior to a 522 order being
24 issued in the United States with TVT-Secur, Ethicon

1 had stopped selling TVT-Secur in other countries
2 already, correct?

3 A. That's my understanding.

4 MR. MORIARTY: Objection.

5 Go ahead.

6 BY MR. JONES:

7 Q. Prior to the 522 order, Ethicon had
8 already stopped selling TVT-Secur in other
9 countries, correct?

10 MR. MORIARTY: Objection.

11 Go ahead.

12 THE WITNESS: I'm not sure the exact
13 dates they stopped selling them. I'm not sure.

14 BY MR. JONES:

15 Q. Prior to Ethicon ceasing sale of the
16 TVT-Secur device inside the United States, Ethicon
17 had already stopped selling the device in
18 Australia, correct?

19 MR. MORIARTY: Objection.

20 Go ahead.

21 THE WITNESS: I'm -- again, I'm not
22 certain of the date they stopped selling it in
23 Australia.

24

1 BY MR. JONES:

2 Q. You just know they stopped selling it
3 in Australia?

4 A. Correct.

5 Q. You know that it was a product recall
6 in Australia, correct?

7 A. I don't know that it was a product
8 recall.

9 Q. You didn't hear that --

10 A. No.

11 Q. -- before today?

12 A. No.

13 Q. You never -- you didn't know before
14 today that Ethicon has issued a product recall on
15 TVT-Secur?

16 A. I don't remember it being called a
17 product recall.

18 Q. You don't remember seeing any documents
19 discussing a recall of TVT-Secur in Australia?

20 A. Not a recall, just that they weren't
21 going to sell it anymore.

22 Q. And why weren't they going to sell it
23 anymore?

24 A. I think that they had doctors that were

1 concerned about the efficacy of it, and probably it
2 wasn't economical for them to sell it there any
3 more.

4 Q. Ethicon stopped selling TVT-Secur in
5 part because of concerns about the efficacy of the
6 device from surgeons, correct?

7 MR. MORIARTY: Objection.

8 THE WITNESS: I would say that's true.

9 BY MR. JONES:

10 Q. Okay. Are you familiar with project
11 Zion?

12 A. That doesn't sound familiar.

13 Q. Project Topa?

14 A. No.

15 Q. Are you -- are you familiar with any
16 projects at Ethicon where they used lighter mesh
17 than TVT for treatment of SUI?

18 A. Not for treatment of SUI, I don't know
19 that.

20 Q. Okay. How about for treatment outside
21 of SUI?

22 A. I'm not familiar with it.

23 Q. Okay. Are you familiar with any
24 projects where Ethicon investigated making the mesh

1 used in TVT softer?

2 A. No.

3 Q. Are you aware of any projects at
4 Ethicon where Ethicon invested making the --
5 investigated making the TVT mesh lighter or less
6 dense?

7 A. No.

8 Q. Are you aware of any projects at
9 Ethicon where Ethicon investigated making the mesh
10 used in TVT partially absorbable?

11 A. No. Not for sling.

12 Q. Okay. You are for POP, though,
13 correct?

14 A. I've heard. I don't know much about
15 it, though.

16 Q. Okay. And what have you heard about
17 it?

18 A. I just know -- I just know they had
19 some sort of absorbable material, maybe Vicryl,
20 that was involved in it.

21 Q. Okay. Why would a company want to
22 market partially absorbable mesh?

23 MR. MORIARTY: Objection. Form.

24 Go ahead.

1 THE WITNESS: I don't know why they
2 would want to do that for -- for specifically
3 stress urinary incontinence. I don't -- for other
4 reasons, I don't know. Again, I'm not familiar
5 with those procedures.

6 BY MR. JONES:

7 Q. You don't know why a company would want
8 to decrease the weight of their mesh used to treat
9 SUI?

10 A. No.

11 Q. Do you know why a company would want to
12 make the pores larger in the mesh to treat SUI?

13 A. No.

14 Q. Do you know why a company would want to
15 make the mesh used to treat SUI softer?

16 A. No.

17 Q. Do you know why a company would want to
18 make the mesh used to treat female SUI less stiff?

19 A. No.

20 Q. Do you believe the TVT-Secur device
21 damaged the brand name of Ethicon?

22 A. I'm not certain about that.

23 Q. You don't know who Aaron Kirkemo is,
24 right?

1 (Reporter interruption for
2 clarification.)

3 MR. JONES: Aaron Kirkemo.

4 MR. MORIARTY: Objection. Asked and
5 answered yesterday.

6 THE WITNESS: No.

7 BY MR. JONES:

8 Q. You didn't learn about who he was last
9 night, did you?

10 A. No. I went to bed last night.

11 Q. Well, you did look at the material
12 safety data sheet, though, correct?

13 A. I did that. Yeah. Well, it was an
14 article with Moalli. It wasn't specifically --

15 Q. Okay. You looked at the cancer article
16 with Moalli?

17 A. Yes. No, no. Yesterday, I looked at
18 the -- at the pore size comparing the
19 different. . .

20 Q. Okay. Yesterday after the deposition
21 you looked at the Moalli article discussing pore
22 size, correct?

23 A. Correct.

24 Q. Okay. What else did you look at after

1 yesterday's deposition?

2 A. I looked through my -- end of the case-
3 specific -- my case-specific reports just to
4 refresh my memory. I've forgotten them all now.

5 Q. But other than the case-specific
6 reports, you just looked at the Moalli 2008
7 article?

8 A. Right.

9 Q. I think we can get out that article
10 real quick.

11 MR. JONES: Exhibit 39.

12 (Whereupon Exhibit 39 was marked as an
13 exhibit.)

14 BY MR. JONES:

15 Q. Is Exhibit 39 the Moalli article you
16 referenced last night? Yes or no?

17 A. I need to look to see if it is, because
18 I just looked at part of it.

19 Yes, it is.

20 Q. I take it you read this article in full
21 last night?

22 A. No, I did not read it in full.

23 Q. Have you ever read this article in
24 full?

1 A. I've read the article in full.

2 Q. Okay. You have read this article in
3 full before, correct?

4 A. Yes.

5 Q. And you -- you looked at it again last
6 night, correct?

7 A. Yes.

8 Q. And you're going to be relying on this
9 article for your opinions in this case, correct?

10 A. Correct.

11 Q. Are there any statements in this
12 article -- go ahead and take some time to look at
13 this article because I'm going to ask you about a
14 couple specific statements.

15 A. Well, go ahead and ask me the question.
16 I'll have to read the whole thing again, if you're
17 going to ask me -- if you want to ask me specific
18 questions, go ahead and ask me specific questions,
19 and if I need to read it, I'll read it. But if you
20 want me to read it now, it's going to take a little
21 while, because I'm not a really fast reader.

22 Q. Okay. I'll try to ask you about
23 specific statements and see if that will help us.

24 Turn to page 656, the second page. Top

1 left-hand corner, 656.

2 Are you with me?

3 A. Yes.

4 Q. Okay. "One of the primary problems in
5 using the TVT is that, as a result of its low
6 stiffness, the mesh easily deforms when tensioning
7 under the urethra. Specifically, pulling the sling
8 gently results in thinning of the mesh,"
9 parenthetical, "permanent deformation, and fraying
10 at the tanged edges."

11 Did I read that correctly?

12 A. Yes.

13 Q. Do you agree or disagree with that
14 statement?

15 A. Well, that's why they have the -- the
16 outer sheath, to prevent that from happening. But
17 that's what you want, is a low-stiffness sling, I
18 would think.

19 Q. Okay. You want a low-stiffness sling,
20 correct?

21 A. Yeah, a sling that has low stiffness.

22 Q. Okay. Why do you want a sling with low
23 stiffness?

24 A. So that it fits the vagina and -- more

1 comfortably for the patient, more comfortably for
2 the physician as it goes in, so that it's not
3 stiff. It molds to the curvature of the tissue.

4 Q. You don't want stiff mesh rubbing up
5 against a woman's vaginal tissues, correct?

6 A. Not necessarily that's rubbing up
7 against the vaginal tissue. The stiffer the mesh
8 is, the less compliant it's going to be, and it's
9 not going to fit, again, like I said, to the
10 curvature of the vaginal tissue.

11 Q. The stiffer the mesh is for treatment
12 of SUI, the less compliant it will be with the
13 woman's anatomy, correct, and tissue?

14 A. The stiffer the mesh?

15 Q. Yeah.

16 A. I would think that's -- yeah.

17 Q. Correct?

18 A. That's -- that's true.

19 Q. Stiffer, the stiffer the mesh, the less
20 compliant it is with a woman's vaginal tissue,
21 correct?

22 A. (Indicating.)

23 Q. Is that fair?

24 A. Yes.

1 Q. Okay. One of the primary problems in
2 using the TVT is that -- a result of its low
3 stiffness, the mesh easily deforms.

4 Do you agree that the mesh easily
5 deforms with TVT?

6 A. If you pull on the mesh itself, tighten
7 it, it will change its shape.

8 Q. Okay. And is Dr. Moalli talking about
9 mechanical-cut mesh or laser-cut mesh in this
10 article?

11 A. I'm not certain which one.

12 Q. You don't have any idea what she's
13 talking about?

14 A. I would have to read the article to see
15 which one --

16 Q. All right. Well, let's go off the
17 record real quick, and you figure out whether she's
18 talking about laser-cut mesh or mechanical-cut
19 mesh.

20 A. (Reviews document.)

21 (Brief recess.)

22 BY MR. JONES:

23 Q. Okay. We're back on the record now,
24 Doctor.

1 A. Okay.

2 Q. You've had some opportunity to review
3 this article again, correct?

4 A. Yes.

5 Q. Do you know what "tanged edges" means?

6 A. I believe it's that they're having them
7 heat sealed, that they are mechanically cut. So I
8 think we're talking about mechanical-cut mesh.

9 Q. Okay. So more likely than not, based
10 on your opinion, this article is talking about
11 mechanical-cut mesh --

12 A. Correct.

13 Q. -- TVT, correct?

14 A. Yes.

15 Q. Okay. Let's go back to page 656, which
16 is the second page. "Consequently, various
17 companies have modified polypropylene sling meshes
18 for easier placement by heat sealing the midportion
19 of the sling that lays flat under the urethra
20 (Boston Scientific) or placing a patented
21 tensioning suture along the longitudinal axis
22 (AMS)."

23 Did I read that correctly?

24 A. Yes.

1 Q. The TVT does not have a tensioning
2 suture, correct?

3 A. No. I've never used the AMS product
4 with tensioning sutures, so I don't know how it
5 works, honestly.

6 Q. Okay. And you've used the AMS SPARC,
7 though, correct?

8 A. In residency.

9 Q. Okay. You've used the AMS Monarc a
10 couple times, correct?

11 A. Probably.

12 Q. Okay. I want to continue reading.

13 "Although the modifications have
14 simplified the technical aspects of sling
15 placement, it is not clear how these changes affect
16 the biomechanical behavior of the sling and,
17 ultimately, clinical outcomes."

18 Do you agree with that statement?

19 A. No, I don't think that the
20 modifications simplified or made the technical
21 aspects of the sling simple or less simple or more
22 simple or easier or harder.

23 Q. Okay. Do you believe that
24 modifications such as heat sealing the mesh may

1 ultimately affect the clinical outcome?

2 A. No.

3 Q. So you disagree with Dr. Moalli that
4 changing the way you cut the mesh may impact the
5 clinical outcome for patients?

6 MR. MORIARTY: Objection. Form and
7 otherwise.

8 THE WITNESS: That's what they're
9 trying to find in here, is if it does. You know,
10 if it may, it may. They want to try to find out if
11 it does.

12 BY MR. JONES:

13 Q. Okay. "In" -- "Indeed, to date, most
14 outcome data failed to distinguish between
15 different type" -- "different types of sling
16 meshes, most likely because the basic biomechanical
17 properties of most sling properties have not been
18 defined."

19 Did I read that correctly?

20 A. You read it correctly.

21 Q. Thanks. Do you agree or disagree with
22 that?

23 A. I don't know if I necessarily agree
24 with that statement or not. I think that the

1 different meshes seem to have fairly similar
2 outcomes, whether or not they have different
3 biochemical properties or not. Didn't seem to
4 affect the clinical outcomes.

5 So, again, this is a supposition that
6 she's making, and I'm -- I'm not sure if that's
7 correct or not.

8 Q. Okay. Have you been shown internal
9 testing by Ethicon that discusses whether laser-cut
10 mesh used in TVT is three times stiffer than
11 mechanical-cut mesh used in TVT?

12 A. I haven't seen it's three times
13 stiffer.

14 Q. You haven't seen that testing?

15 A. No.

16 Q. Okay. Ethicon didn't show that to you?

17 A. I haven't seen it.

18 Q. "It is knowledge of the properties of
19 the sling material that surgeons have the greatest
20 knowledge deficit and consequently are completely
21 dependent on the mesh information supplied by a
22 representative of the vendor."

23 Did I read that correctly?

24 A. I don't know where you are.

1 Q. Page 656. It's highlighted. Lucky.

2 A. Where is that?

3 Q. "It is troubling" -- or "It is
4 knowledge."

5 A. Okay.

6 Q. "It is knowledge of the properties of
7 the sling material that surgeons have the greatest
8 knowledge deficit and consequently are completely
9 dependent on the mesh information supplied by a
10 representative of the vendor."

11 Did I read that correctly?

12 A. Yes, you read it correctly.

13 Q. Do you agree with that statement?

14 A. I would say that they say "completely
15 dependent." I don't think it's completely
16 dependent. I think there are studies that are --
17 on these type of things that are available if you
18 want to look at them or find them.

19 Q. If we take out "completely," do you
20 agree with that statement?

21 A. I would say it's partially dependent.

22 Q. "It is knowledge of the properties of
23 the sling material that surgeons have the greatest
24 knowledge deficit."

1 Do you agree with that?

2 A. No. I think surgeons know what the
3 properties of the slings are.

4 Q. So you disagree with that?

5 A. Yes.

6 Q. You disagree with Dr. Moalli, correct?

7 A. I disagree with the statement she made.

8 Q. You disagree with the statement
9 Dr. Moalli makes in this peer-reviewed medical
10 journal, correct?

11 A. Yes.

12 Q. And you've never published in any
13 peer-reviewed medical journal on female SUI,
14 correct?

15 A. No.

16 Q. "Even more problematic is that many of
17 the representatives have little knowledge of the
18 biomechanical factors that may be relevant and tend
19 to focus on aspects of the sling which facilitate
20 the operation for the surgeon."

21 Did I read that correctly?

22 A. Yes.

23 Q. Do you agree or disagree with that
24 statement?

1 MR. MORIARTY: Objection.

2 Go ahead.

3 THE WITNESS: I guess I don't know what
4 she means by "representatives." I don't know if
5 she's --

6 BY MR. JONES:

7 Q. Ethicon sales reps.

8 Do you agree or disagree?

9 A. I think that they know what -- what the
10 biomechanical factors are.

11 Q. So you disagree here with Dr. Moalli as
12 well, correct?

13 A. Yes.

14 Q. Okay. Turn to page 661. "Gynemesh was
15 different from that of all the other samples
16 tested. Gynecare samples permanently elongated by
17 17 plus or minus within the margin of error 4
18 percent, indicating that, although very little
19 force applied, there is irreversible deformation of
20 the TVT."

21 Did I read that correctly?

22 A. Yes.

23 Q. Do you agree that Gyne- -- do you agree
24 that Dr. Moalli in her testing found that Gynecare

1 mesh was different from that of all other samples
2 she tested?

3 A. In this one respect. Reading the
4 article, she says that they're all very similar.
5 So in this one respect there is a difference.

6 Q. Okay. Okay. Then turn to page 663.
7 You stole my highlighted copy. How -- second
8 column on the right. "In contrast, a high-
9 stiffness material may not yield," parenthetical,
10 "elongate, with the application of even high
11 loads," parenthetical, "a very heavy cough, and
12 consequently would have an increased likelihood of
13 erosion into the bladder or urethra."

14 Did I read that correctly?

15 A. Where is that? That's not part of the
16 highlighted part.

17 Q. Yeah, I know. Forget the -- below the
18 highlighted. Yeah. "In contrast."

19 A. "In contrast, the high-stiffness
20 material may not yield"?

21 Q. Yeah.

22 A. Okay.

23 Q. "In contrast, a high stiffness material
24 may not yield," parenthetical "elongate, with the

1 application of even high loads," parenthetical, "a
2 very high" -- "a very heavy cough, and consequently
3 would have an increased likelihood of erosion into
4 the bladder or urethra."

5 A. Yes.

6 Q. I read that correctly?

7 A. Correct.

8 Q. Do you agree or disagree with that
9 statement?

10 A. I agree with that statement.

11 MR. JONES: Okay. I think that's all
12 the questions I have.

13 MR. MORIARTY: Let me just ask you a
14 couple.

15

16 EXAMINATION BY MR. MORIARTY:

17 Q. On this page 663 of the Moalli article
18 that he was just talking about, in the second
19 column, is -- are Moalli and her coauthors
20 speculating about possible benefits that the
21 stiffness profile of this -- of these meshes have
22 regarding clinical complications like erosion?

23 A. I'm sorry. Say that --

24 MR. JONES: Object to form.

1 THE WITNESS: -- first part of the
2 question again.

3 BY MR. MORIARTY:

4 Q. Page 663 --

5 A. Right.

6 Q. -- on the second column, are Moalli and
7 her coauthors speculating about possible benefits
8 that this stiffness profile would have regarding
9 clinical complications?

10 MR. JONES: Objection.

11 BY MR. MORIARTY:

12 Q. By lowering the rate of erosions of a
13 sling?

14 MR. JONES: Same objection.

15 THE WITNESS: Yes.

16 BY MR. MORIARTY:

17 Q. Okay. And at page -- at the second
18 page of this article, does it say that for
19 simplicity of data presentation, they used the
20 Gynecare TVT as the gold standard and defined the
21 behavior of five newer versions relative to it?

22 A. Correct.

23 Q. Is "Urology" a journal that you
24 receive?

1 A. I -- yes. I -- our group receives it.
2 I don't receive it personally, but our practice
3 receives it.

4 Q. Do you periodically review it for
5 articles of interest?

6 A. Yes.

7 Q. So if there was an article in that
8 journal in 2012 about promises made and promises
9 broken with TVT-S, is it possible that you reviewed
10 that article back then?

11 A. It's possible.

12 Q. When the 522 order came out, did FDA
13 say that the remaining stocks couldn't be used?

14 A. No, they did not say that.

15 MR. JONES: Objection.

16 BY MR. MORIARTY:

17 Q. Was it recalled?

18 MR. JONES: Objection.

19 THE WITNESS: No.

20 BY MR. MORIARTY:

21 Q. Did FDA ever say it was unsafe or
22 ineffective?

23 A. No.

24 Q. In your experience and from your review

1 of the Level 1 medical literature, is the erosion
2 rate of -- of any of the TVT products, Retropubic,
3 Obturator, or Secur, higher than 10 percent?

4 A. No.

5 Q. Mr. Jones asked you some questions
6 about one of the contracts and whether you had to
7 get approval of all the things you discussed with
8 the doctors in a proctoring session.

9 Do you remember that?

10 A. Yes.

11 Q. In a proctoring session, would you
12 routinely discuss the published medical literature?

13 A. Yes.

14 Q. You were asked some questions about
15 complication rates. I want to follow up on that.

16 Throughout the years of your practice,
17 have you consistently had meetings with your
18 partners about things affecting the practice,
19 including types of surgeries you do and
20 complication rates?

21 MR. JONES: Objection.

22 THE WITNESS: Yes.

23 BY MR. MORIARTY:

24 Q. Over the course of your career, have

1 you consistently thought about and analyzed your
2 own results in comparison with published medical
3 literature?

4 MR. JONES: Objection.

5 THE WITNESS: Yes.

6 BY MR. MORIARTY:

7 Q. Is that true even though you haven't
8 kept a registry and kept detailed information about
9 that?

10 A. Yes.

11 MR. JONES: Objection.

12 BY MR. MORIARTY:

13 Q. Did you ever in your surgical practice
14 notice a difference in performance or outcomes
15 between laser- or mechanically-cut mesh?

16 A. No.

17 MR. JONES: Objection.

18 BY MR. MORIARTY:

19 Q. Mr. Jones asked you some questions
20 about long-term safety studies regarding TVT. I
21 want to follow up on that.

22 So far as the mesh itself is concerned,
23 the mesh used in the TVT Retropubic, Obturator, and
24 Secur, does long-term data about the mesh apply

1 across the different types?

2 MR. JONES: Objection.

3 THE WITNESS: Yes.

4 BY MR. MORIARTY:

5 Q. Is erosion a risk of all polypropylene
6 mesh implants?

7 A. Yes.

8 Q. Not just Ethicon products?

9 A. Correct.

10 Q. In your own personal experience, was
11 TVT-Secur safe?

12 A. Yes.

13 Q. Was it effective?

14 A. Yes.

15 Q. Were your complication rates less
16 than -- I'm sorry.

17 Were your erosion rates less than 2 or
18 3 percent --

19 MR. JONES: Objection.

20 BY MR. MORIARTY:

21 Q. -- with TVT-Secur?

22 A. Yes.

23 MR. JONES: Objection.

24

1 BY MR. MORIARTY:

2 Q. You were asked some questions yesterday
3 about these advisory board documents that were
4 exhibits, like 9, 10, and 11.

5 Had you ever actually seen those
6 particular documents before yesterday?

7 A. No, I don't remember them.

8 Q. You were asked some questions yesterday
9 about the safety profile of mini-slings versus
10 Obturator and Retropubic. I'll follow up on that.

11 What is the theoretical safety
12 advantage that Secur had over Retropubic or
13 Obturator?

14 A. The introducers didn't have to pass
15 through the Obturator canal or behind the pubic
16 bone, so there would be directly less risk of
17 damaging the Obturator nerve or vessels or
18 potentially, with the Retropubic device, damaging
19 bowel, bladder -- it would be less likely to damage
20 the bladder.

21 Q. Okay.

22 A. Smaller piece of mesh.

23 Q. So when you have used medical devices
24 other than TVT, TVT Obturator and TVT-Secur, have

1 you from time to time reviewed their instructions
2 for use?

3 A. Yes.

4 Q. And is that greater body of information
5 that you gained by reviewing IFUs of other products
6 part of the body of information that you have in
7 which you form opinions in this case about
8 Ethicon's IFUs?

9 MR. JONES: Objection. Asked and
10 answered.

11 THE WITNESS: Yes, I do.

12 BY MR. MORIARTY:

13 Q. The opinions that you intend to express
14 about the safety and efficacy of the TVT products,
15 are those opinions that you have held for many
16 years while you were using those devices?

17 A. Yes.

18 Q. Are those just opinions you came up
19 with for purposes of litigation?

20 MR. JONES: Objection.

21 THE WITNESS: No.

22 BY MR. MORIARTY:

23 Q. Do you have some experience in
24 reviewing pathology slides or pathology reports

1 from the surgeries that you perform?

2 A. Yes.

3 MR. JONES: Objection.

4 THE WITNESS: Yes, I do. And I
5 continue to review pathology results on prostate
6 cancer cases. We were trained that in residency,
7 too.

8 MR. MORIARTY: Okay. That's all I
9 have.

10

11 FURTHER EXAMINATION BY MR. JONES:

12 Q. Just one or two questions.

13 MR. MORIARTY: Before you start, if
14 it's going to be one or two, I won't do the math on
15 your time, but you actually are getting close to
16 seven hours.

17 MR. JONES: Okay. Okay. I appreciate
18 that. It won't be long.

19 BY MR. JONES:

20 Q. You listed a -- as one of the potential
21 safety advantages of TVT-Secur being the use of a
22 smaller piece of mesh, correct?

23 A. Yes.

24 Q. Why is using a smaller piece of mesh in

1 TVT-Secur a potential safety benefit?

2 A. I think that there would be less
3 inflammation caused by a smaller piece of mesh.

4 Q. Less mesh equals less inflammation
5 inside the woman, correct?

6 A. I think that goes to reason.

7 Q. And just for verification, you will be
8 relying on the AMS MiniArc-Precise IFU in this
9 litigation, correct?

10 A. I'll be relying on my -- my
11 experience --

12 Q. Experience --

13 A. -- with IFUs in general.

14 Q. So we can ask you about your experience
15 reviewing the AMS MiniArc-Precise at trial,
16 correct?

17 A. Yes.

18 Q. Okay. And we can ask you about the
19 contents of the AMS MiniArc-Precise IFU, correct?

20 A. Yes.

21 Q. And how those compare against the
22 contents of the TVT-Secur IFU, correct?

23 A. Yes.

24 Q. Do you standby the testimony that you

1 gave last night under oath?

2 A. Last night? Excuse me?

3 Q. Do you stand by the testimony you gave
4 last night under oath?

5 A. Oh, yes.

6 Q. You don't -- nothing you want to
7 change?

8 A. No.

9 Q. Is TVT-Secur the gold standard?

10 A. Is TVT-Secur the gold standard now?

11 Q. Yes.

12 A. No.

13 MR. JONES: That's it. I've got more,
14 but I won't.

15 MR. MORIARTY: Okay. We're done.

16 (Proceedings concluded at 12:27 p.m.)

17

18

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1 C E R T I F I C A T E

2 STATE OF TENNESSEE)

COUNTY OF DAVIDSON)

3 I, Lise S. Matthews, RMR, CRR, CRC, LCR
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4 and for the State of Tennessee, do hereby certify
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5 the transcript is a true and accurate record to the
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